

FINDING OF NO SIGNIFICANT IMPACT

1. PROPOSED ACTION: Because of the current threat of biological warfare and its continuing proliferation, there is an urgent need to protect our fighting men and women who go in harms way. The proposed action (preferred alternative) and subject of this Programmatic Environmental Assessment (PEA) is the implementation and operation of the Joint Vaccine Acquisition Program (JVAP) through which the Department of the Army (DA) proposes to develop, produce, store, test, and field vaccines for biological defense which are otherwise unavailable. The JVAP is being implemented by the Department of Defense (DoD) through the Joint Program Office for Biological Defense (JPO BD), for which the DA is the lead agency.

The primary objective of the JVAP is to develop, produce, store, test, and field sufficient quantities of U.S. Food and Drug Administration (FDA) licensed vaccines to implement U.S. government policy for protecting its armed forces against death and disease resulting from biological warfare agents. A competitively awarded JVAP prime systems contractor will provide a centralized, integrated management approach to designing, planning, and managing the complexities of vaccine development and licensure. The DA has sought proposals from qualified and interested parties through the publication of JVAP Request for Proposal (DAMD17-95-R-5020).

2. ALTERNATIVES CONSIDERED: During the preparation of this PEA, three reasonable alternatives in addition to the proposed action were identified. The reasonable alternatives identified included the cessation of all JVAP activities now and in the future (Alternative II - the no-action alternative); the conduct of current and currently planned JVAP activities in a consolidated government facility (Alternative III), and the conduct of current and currently planned JVAP activities at a consolidated contractor facility (Alternative IV).

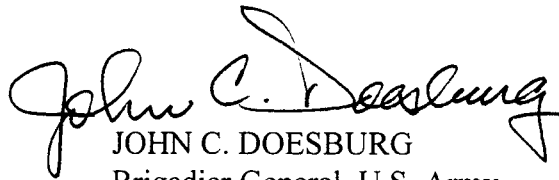
3. ENVIRONMENTAL CONSEQUENCES AND MITIGATION MEASURES:

Significant adverse environmental impacts are unlikely to result from implementation of the proposed action. The preferred alternative includes the use of state-of-the-art work practice and engineering controls, and adherence to existing regulations and guidance minimizes potential risks to the human environment, including workers and the general public. Further, adherence to health, environmental, and safety requirements applicable to the development, production, and use of JVAP products will minimize risk to the workforce and ensure the effectiveness of these products for protection against biological warfare agents.

4. FACTORS CONSIDERED IN THE FINDING OF NO SIGNIFICANT IMPACT: The PEA systematically reviews the nature of the proposed action and associated risks and issues. Particular attention is given to protection of the workforce and the surrounding community as well as associated risks. Reasonable alternatives with regard to needs of the United States and the U.S. Army and potential adverse effects on the environment are evaluated.

5. CONCLUSIONS: The principal conclusion of this PEA is that implementing the JVAP in its current and planned scope (Alternative I, the preferred alternative) will likely result in only negligible or minor environmental impacts. If no action is taken (Alternative II), these potential

negligible or minor environmental impacts would be eliminated. The implementation of either Alternative III or IV will likely result in greater environmental impact than the preferred alternative or the no-action alternative because of the probable need for construction or major renovation associated with these alternatives, and the consolidation of all environmental impacts in one geographical area.

A handwritten signature in black ink, reading "John C. Doesburg". The signature is fluid and cursive, with the first name "John" being the most prominent.

JOHN C. DOESBURG
Brigadier General, U.S. Army
Joint Program Manager
for Biological Defense

Comments on this Finding of No Significant Impact may be directed to Department of the Army, JOINT VACCINE ACQUISITION PROGRAM, PROJECT MANAGEMENT OFFICE, JVAP-PMO (ATTN: MR. BRUCE KAY), 568 DOUGHTEN DRIVE, SUITE 100, FORT DETRICK, MD 21702-5040 and must be received by October 17, 1997. Copies of the PEA are available for review by the public at the Columbus Metropolitan Library, 96 S. Grant Ave., Columbus, OH, 43215; East Shore Library, 4501 Ethel St., Harrisburg, PA, 17109; Frederick County Public Library, 110 E. Patrick St., Frederick, MD, 21701; Hurt Battelle Memorial Library, 270 Lily Chapel Rd., W. Jefferson, OH, 43162-1202; Ingham County Library, 4538 Elizabeth Rd., Lansing, MI, 48917; Lansing Public Library, 717 Allegan, Lansing, MI, 48909; Monroe County Public Library, Pocono Township Branch, Township Municipal Building, Rte. 611, Tannersville, PA, 18372; Montgomery County Public Library, Rockville Branch, 99 Maryland Avenue, Rockville, MD, 20850; Montgomery County Public Library, Twinbrook Branch, Reference Department, 202 Meadow Hall Drive, Rockville, MD, 20851; Post Library, Building 501, Ft. Detrick, Frederick, MD, 21702-5000; and the Tyson-Pimmit Library, 7884 Leesburg Pike, Falls Church, VA, 22043.

NOTICE OF AVAILABILITY

FINAL PROGRAMMATIC ENVIRONMENTAL ASSESSMENT (FPEA) AND FINDING OF NO SIGNIFICANT IMPACT (FNSI) FOR THE JOINT VACCINE ACQUISITION PROGRAM

The U.S. Department of the Army (DA) announces the availability for public review and comment of an FPEA and FNSI for the Joint Vaccine Acquisition Program (JVAP). The primary objective of the JVAP is to develop, produce, store, test, and field sufficient quantities of U.S. Food and Drug Administration (FDA) licensed vaccines to implement U.S. government policy for protecting its armed forces against biological warfare agents. Because of the current threat of biological warfare and its continuing proliferation, there is an urgent need to protect our fighting men and women who go in harm's way. The JVAP is implemented by the Department of Defense (DoD) through the Joint Program Office for Biological Defense (JPO BD), for which the DA is the lead agency. The JVAP FPEA characterizes and assesses the possible and probable environmental consequences associated with the JVAP as proposed, and the alternatives considered. The FPEA concludes that the proposed JVAP activities and the alternatives analyzed are not likely to have significant adverse effects upon the quality of the environment.

Alternatives:

- a. Implement and operate the JVAP through which the Army proposes to develop, produce, store, test, and field vaccines for biological defense which are otherwise unavailable (Preferred Alternative).
- b. No action (cessation of all JVAP activities now and in the future).
- c. Conduct current and currently planned JVAP activities in a consolidated government facility.
- d. Conduct current and currently planned JVAP activities at a consolidated contractor facility.

The JVAP FPEA/FNSI are available for public review and comment. Copies are available for review at the Columbus Metropolitan Library, 96 S. Grant Ave., Columbus, OH, 43215; East Shore Library, 4501 Ethel St., Harrisburg, PA, 17109; Frederick County Public Library, 110 E. Patrick St., Frederick, MD, 21701; Hurt Battelle Memorial Library, 270 Lily Chapel Rd., W. Jefferson, OH, 43162-1202; Ingham County Library, 4538 Elizabeth Rd., Lansing, MI, 48917; Lansing Public Library, 401 South Capital Street, Lansing, MI 48933-2037; Library of Michigan, 717 Allegan, P.O. Box 30007, Lansing, MI, 48909; Monroe County Public Library, Pocono Township Branch, Township Municipal Building, Rte. 611, Tannersville, PA, 18372; Montgomery County Public Library, Rockville Branch, 99 Maryland Avenue, Rockville, MD, 20850; Montgomery County Public Library, Twinbrook Branch, Reference Department, 202 Meadow Hall Drive, Rockville, MD, 20851; Post Library, Building 501, Ft. Detrick, Frederick, MD, 21702-5000; and the Tyson-Pimmit Library, 7584 Leesburg Pike, Falls Church, VA, 22043. A copy of the document may also be obtained by writing to: JOINT VACCINE ACQUISITION PROGRAM PROJECT MANAGEMENT OFFICE, JVAP-PMO (ATTN: MR. BRUCE KAY), 568 DOUGHTEN DRIVE, SUITE 100, FORT DETRICK, MD 21702-5040; or downloaded from the internet at <http://www.armymedicine.army.mil/jvap-fpea>. Mr. Kay is the DA clearinghouse for requests for the JVAP FPEA/FNSI, and documentation from previous environmental analyses referenced in the FPEA. Written comments on the final EA should be submitted to the same address and must be received no later than October 17, 1997.

Joint Vaccine Acquisition Program

Final Programmatic Environmental Assessment

Department of the Army
Joint Program Office for Biological Defense



September 1997



**Joint Vaccine Acquisition Program
Joint Project Management Office (JVAP-PMO)**
568 Doughten Drive Suite 100
Fort Detrick, Maryland 21702-5040

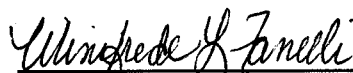


**JOINT VACCINE ACQUISITION PROGRAM
PROGRAMMATIC ENVIRONMENTAL ASSESSMENT**


August 1997

Prepared by:
The Joint Vaccine Acquisition Program
Project Management Office (JVAP PMO)

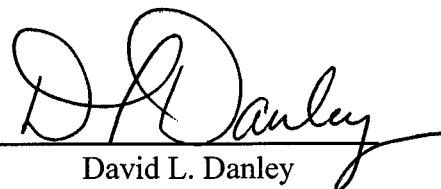
Reviewed by:


Winifrede L. Fanelli
Project Manager (Acting)
JVAP PMO

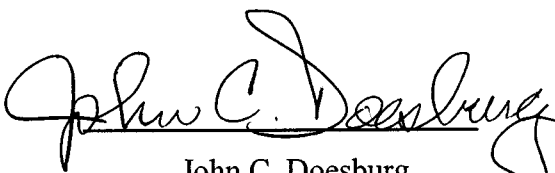
Reviewed by:

for  MAJ, MS
Robert J. Carton, Ph.D.
Environmental Officer
US. Army Medical Research
and Materiel Command

Reviewed by:


David L. Danley
Colonel, United States Army
Deputy Program Manager (Acting)
Joint Program Office for Biological Defense

Approved by:


John C. Doesburg
Brigadier General, United States Army
Program Manager for
Joint Program Office for Biological Defense

Joint Vaccine Acquisition Program
Final Programmatic Environmental Assessment

JOINT VACCINE ACQUISITION PROGRAM
FINAL PROGRAMMATIC ENVIRONMENTAL
ASSESSMENT

Joint Vaccine Acquisition Program
Final Programmatic Environmental Assessment

EXECUTIVE SUMMARY

This Programmatic Environmental Assessment (PEA) was prepared in accordance with guidance provided in Army Regulation (AR) 200-2, *Environmental Effects of Army Actions*, dated December 23, 1988, implementing the National Environmental Policy Act (NEPA) (42 USC 4321-4347). This PEA, *The Joint Vaccine Acquisition Program Programmatic Environmental Assessment*, was prepared by the Joint Program Office for Biological Defense (JPO BD) with assistance from Science Applications International Corporation (SAIC) under Government Contract Number DAMD17-93-C-3141.

Because of the current threat of biological warfare and its continuing proliferation, there is an urgent need to protect our fighting men and women who go in harm's way. The proposed action (preferred alternative) and subject of this PEA is the implementation and operation of the Joint Vaccine Acquisition Program (JVAP). The Department of the Army (DA), as the lead agency for the Department of Defense (DoD), proposes to use the JVAP to develop, produce, store, test, and field vaccines for biological defense. These vaccines are otherwise unavailable. The JVAP has been authorized and funded by the U.S. Congress and is being implemented by the DoD through JPO BD.

The primary objective of the JVAP is to develop, produce, store, test, and field sufficient quantities of U.S. Food and Drug Administration (FDA) licensed vaccines to implement U.S. government policy for protecting its armed forces against death and disease resulting from biological warfare agents. A competitively awarded prime systems contract is a major element of the JVAP. The DA has sought contract proposals from qualified and interested parties through the publication of the JVAP Request for Proposal (RFP) (DAMD17-95-R-5020). The selected prime contractor will provide management services, personnel, facilities, equipment, materials, supplies, and documentation necessary to develop and produce FDA-licensed vaccines as specified in the DoD JVAP RFP.

Three alternatives to the proposed action were considered including discontinuing current and currently proposed JVAP activities (Alternative II, no-action); conducting proposed JVAP activities in a consolidated government facility (Alternative III); and conducting proposed JVAP activities in a consolidated contractor facility (Alternative IV). This PEA characterizes the reasonably foreseeable environmental impacts, including impacts to human health, that might result from the proposed JVAP (Alternative I, the preferred alternative) and the alternatives considered.

The analysis of the proposed action considers that some JVAP activities will be conducted over an extended period of time and at yet to be determined geographical locations. The potential environmental impacts of the proposed JVAP and the alternatives are assessed by evaluating observed environmental impacts at biomedical facilities performing similar or identical activities. Relevant analyses of those facilities are used to determine if significant environmental impacts are likely to result from the conduct of proposed JVAP activities or the alternatives. This PEA

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concludes that it is unlikely that the proposed JVAP and the alternatives analyzed will result in a significant impact on the environment. However, because of the extended duration of the JVAP and uncertain sites of program execution, additional site-specific evaluation may be needed in the future to ensure that potential environmental consequences are evaluated in accordance with the NEPA and AR 200-2.

The principal conclusion¹ of this PEA is that implementing the JVAP in its current and planned scope (Alternative I, the preferred alternative) will likely result in only negligible or minor environmental impacts. If no action is taken (Alternative II), these potential negligible or minor environmental impacts would be eliminated. The implementation of either Alternative III or IV will likely result in greater, although not significant, environmental impact than the preferred alternative or the no-action alternative because of the probable need for construction or renovation associated with these alternatives, and the consolidation of all environmental impacts in one geographical area.

¹ During the preparation of this document, the FDA conducted an inspection of Michigan Biologic Products Institute (MBPI) (see appendix E). This inspection concerns MBPI's implementation of FDA regulatory requirements. Appendix E addresses issues raised by the FDA in the March 11, 1997 letter to MBPI in context of this programmatic assessment.

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1.0 PURPOSE AND NEED FOR THE JVAP

1.1 INTRODUCTION

Because of the current threat of biological warfare and its continuing proliferation, there is an urgent need to protect our fighting men and women who go in harms way. The proposed action (preferred alternative) and subject of this Programmatic Environmental Assessment (PEA) is the implementation and operation of the Joint Vaccine Acquisition Program (JVAP). Through the JVAP, the Department of the Army (DA) proposes to implement U.S. government policy for protecting its armed forces against death and disease resulting from biological warfare agents by developing and producing otherwise unavailable biological defense vaccines. Proposed JVAP operations encompass the advanced stages of product development, the life cycle of vaccine production, stockpiling (storage of adequate quantities for future times of need), and fielding (the distribution of product to Department of Defense (DoD) medical logistics divisions). Some activities which are being conducted by government and private sector organizations involve ongoing efforts associated with the development of biological defense vaccines and will become a part of the JVAP once fully implemented. These ongoing activities are described in Section 2.0. A full description of the planned program is also located in Section 2.0. A list of the vaccines and toxoids scheduled for development and production is located in Section 2.2.

It is not within the proposed scope of the JVAP to provide the services associated with the DoD medical distribution chain, such as those actions and decisions leading up to and including the administration of vaccines to soldiers. Decisions to administer vaccines are made by the Secretary of Defense based upon advice from the Assistant Secretary of Defense for Health Affairs, and are implemented through the Secretaries of the military departments and the Joint Chiefs. Biological defense vaccines will be administered to military personnel through DoD's medical care delivery systems.

The JVAP has been authorized and funded by the U.S. Congress and is being implemented by the DoD through the Joint Program Office for Biological Defense (JPO BD), with the DA as the lead agency. A competitively awarded prime systems contract is a major element of the JVAP. The DA has sought contract proposals from qualified and interested parties through the publication of the JVAP Request for Proposal (RFP) (DAMD17-95-R-5020). The selected prime contractor will provide management services, personnel, facilities, equipment, materials, supplies, and documentation necessary to accomplish the tasks specified in the DoD JVAP RFP.

In accordance with the National Environmental Policy Act (NEPA) (42 USC 4321-4370d), each federal agency must consider the possible environmental impacts of its proposed major actions. NEPA requires that the interested and affected public be informed of the environmental analyses performed. The Council on Environmental Quality (CEQ), Executive Office of the President, has promulgated regulations implementing NEPA (40 CFR 1500-1508). Army Regulation (AR) 200-2, *Environmental Effects of Army Actions*, dated December 23, 1988 (32 CFR 651), is the DA implementation of NEPA and CEQ regulations. AR 200-2 requires that the DA prepare

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environmental documentation in the form of an environmental assessment (EA) to determine the extent of environmental impacts of a project and decide whether or not those impacts are significant.

This programmatic assessment characterizes the reasonably foreseeable environmental impacts that might result from implementing the range of activities required to develop, produce, store, test, and field vaccines. It addresses activities which will be conducted over a period of time and in various geographical locations. The time frame required for implementing the full extent of the proposed action is lengthy (greater than 10 years) and not all sites of JVAP performance have been determined. It is therefore necessary to defer the full discussion of some anticipated future actions. NEPA, CEQ regulations, and AR 200-2 provide for the application of programmatic analyses to future actions. In accordance with CEQ regulations (40 CFR 1502.4(c), 1502.20, and 1508.23) and AR 200-2 (Section 2-6, part c), programmatic analyses such as this one can be used to facilitate future, related analyses while eliminating repetitive discussions of similar issues. Should subsequent NEPA analyses be required for the JVAP, such analyses can focus on the key issues concerning site-specific actions or the start-up of new phases of the action. These subsequent NEPA analyses can summarize the issues discussed in the broader assessment provided in this PEA (see Section 1.3).

Both NEPA and AR 200-2 require that EAs be periodically reexamined to assure that substantive changes in an action have been analyzed for environmental impact. It will be necessary for the DA to assess changes to JVAP activities to determine if they are substantive and require additional environmental analyses. In accordance with both NEPA and AR 200-2, subsequent NEPA analyses for JVAP actions may be tiered to this programmatic document (see Section 1.4).

The DA and the U.S. Food and Drug Administration (FDA) each have federal agency responsibility for considering the potential environmental impacts of the JVAP. The DA has lead responsibility for NEPA compliance for actions involving contract selections, and program administration, and acts as the managing sponsor for actions involving the development, production, and storage of product. As the federal agency with authority to regulate and license biological products, the FDA is the lead agency for consideration of the potential environmental impacts associated with the products that it licenses (see Sections 2.4.3.3 and 4.3) and the operations that it regulates.

1.2 PURPOSE AND NEED FOR THE JVAP

The JVAP is needed to develop and produce vaccines that are otherwise unavailable and for which a need has been determined. The JVAP implements U.S. policy regarding medical biological defense and the requirement to develop, produce, and stockpile FDA-licensed vaccines (DoD Directive 6205.3, Immunization Program for Biological Warfare Defense). A detailed discussion of the biological warfare threat and defense is located at Appendix A. The Deputy Secretary of Defense identified biological defense as a high priority requirement in a memorandum dated August 26, 1991. The Joint Chiefs of Staff (JCS) articulated the importance of medical

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biological defense products to military readiness in its Mission Needs Statement for Biological Defense dated August 31, 1992. The JCS document established an urgent requirement for creating a vaccine production and stockpile capability. The JCS recommended that the Defense Acquisition Board (DAB) oversee such a program and on June 28, 1993, the Under Secretary of Defense (Acquisition and Technology) approved an Acquisition Decision Memorandum establishing the JPO BD. The Charter for the JPO BD was approved by the Deputy Secretary of Defense on May 19, 1994 (Appendix B). In this Charter, the Joint Program Manager for Biological Defense (JPM BD) was assigned responsibility for the development, procurement and stockpiling of FDA-licensed vaccines for the purpose of biological defense. On January 26, 1996, the Deputy Secretary of Defense directed the JPM BD to initiate a program using a prime systems contract approach (i.e., the JVAP) to develop, procure and stockpile such vaccines (Program Budget Decision Number 724; subject, Counterproliferation).

The need for the JVAP and contractor support committed to implementing the complex process of developing and producing FDA-licensed biological defense vaccines results from the unavailability of such vaccines for purchase. The current medical biological defense industrial base for the production of biological defense vaccines is inadequate to achieve the needs identified by the DoD. The U.S. private sector vaccine production base in general has undergone considerable decline since 1970. This decline has resulted from several factors including costs associated with increasing regulatory requirements, poor return on investment, and liability. These factors coupled with the nature of and relatively small potential market for biological defense vaccines make it unlikely that private sector pharmaceutical companies would invest in their development and production. The only FDA-licensed vaccine currently available for protection against likely biological warfare agents is the vaccine against anthrax.

1.3 ASSESSMENT METHODOLOGY

This PEA describes and characterizes the activities associated with implementing the proposed action (see Section 2.0). It identifies several reasonable alternatives to the proposed action (see Section 3.0). This PEA then discusses the components of the environment that might be potentially impacted by the proposed action and analyzes the proposed action and identified alternatives for their potential environmental consequences (see Section 4.0). This analysis considers impacts that are expected to result from routine operations, from the potential environmental impacts that might occur after several years and in conjunction with impacts associated with other activities in the area, and as a result of an accident or incident.

In considering environmental consequences to the extent feasible and appropriate in this programmatic document, this PEA also examines the potential impacts of the proposed action on human health. The health of vaccine development and production workers and the public is considered. More specific environmental analyses may be undertaken as necessary and appropriate as the program progresses (see Section 4.3). Although the deployment and administration of vaccines are outside the scope of the JVAP, the potential health impacts to vaccine recipients (reasonably foreseeable consequences of the proposed action) are considered

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along with the measures currently in place to mitigate and monitor potential negative health impacts (see Sections 2.5.7.3 and 4.4.18.3).

This PEA defers detailed analyses of future issues related to the conduct of the program at a specific geographical location, and issues related to specific products. Separate environmental analysis [e.g., Records of Environmental Consideration (RECs), EAs, Environmental Impact Statements (EISs)] may be required should construction of new facilities be necessary for the JVAP (see Section 1.1). Environmental impacts of vaccines and/or other biologic products licensed and regulated by the FDA will be assessed at the point of Investigational New Drug (IND) or New Drug Application (NDA) submittals (see 2.4.3.3) and in anticipation of FDA licensing. FDA's decision regarding whether to issue a product license will be made only after appropriate consideration of the environmental impacts.

1.4 PREVIOUS NEPA ANALYSES

This PEA incorporates appropriate and relevant prior NEPA analyses (updated where changes have occurred) which assessed actions with similar activities and potential impact to those of the proposed action (see Section 2.0 and Section 4.0)². Several elements of the JVAP have been previously examined within the context of NEPA since they were conducted prior to the establishment of the JPO BD. Because of the similarities between these actions and the proposed action, the standards previously established for weighing potential impacts have been considered and applied here where applicable. This approach entails referencing and summarizing specific analyses, discussions, and conclusions of those documents without providing detailed discussions in the present PEA.

Biological defense biomedical and microbiological activities used in vaccine development and production have been previously examined in a programmatic NEPA document and site-specific EAs. The safety, containment engineering, and work practice controls of planned JVAP research and development are comparable to those evaluated in the *Biological Defense Research Program Final Programmatic Environmental Impact Statement* (BDRP FPEIS, 1989) and the *U.S. Army Medical Research Institute of Infectious Disease EA* (USAMRIID EA, 1991). These assessments evaluated general laboratory activities; laboratory and animal studies involving the use of biological defense-specific etiologic agents (microorganisms and toxins); decontamination of materials, equipment, and/or laboratories; and the disposal of biological materials. These analyses also considered the transport of biohazardous organisms into and out of facilities; waste stream management; facility operation and maintenance; animal care and use; and the testing of products or product prototypes in human volunteers. Research, development, and the production of pilot lots of vaccines (vaccinia; Western, Eastern, and Venezuelan equine encephalitis; Q-fever; tularemia; and anthrax) were previously examined in *The Salk Institute-Government Services Division EA* (TSI-GSD EA, 1992). The activities and impacts of producing large quantities of

² Copies of these previous environmental analyses can be obtained by writing to Mr. Bruce Kay at JOINT VACCINE ACQUISITION PROJECT MANAGEMENT OFFICE, JVAP-PMO (ATTN: MR. BRUCE KAY), 568 DOUGHTEN DRIVE, SUITE 100, FORT DETRICK, MD 21702-5040.

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FDA-licensed vaccine (anthrax) were examined in the *Anthrax Vaccine Production and Testing at the Michigan Department of Public Health EA* (MDPH EA, 1993). Vaccine efficacy testing (botulinum toxoid) was examined in the MDPH EA and within the *EA for Battelle's BL-3 Facility* (Battelle EA, 1993).

1.5 PUBLIC PARTICIPATION

A draft of the PEA was distributed to the public, private sector and government entities, including elected officials, identified as having possible interest in the proposed action (see Appendix F). A Federal Register notice published on June 11, 1997 (Appendix G) announced availability of the draft PEA and solicited comments during a public comment period ending on July 14, 1997. The draft PEA was also made available for review in selected public libraries, and its availability was announced in newspapers (Appendix G). Finally, the draft PEA and the NEPA documents it referenced were made available electronically on the world wide web.

The public was encouraged to review and comment on this draft PEA. Comments were received from three private organizations, one state agency and two federal agencies (Appendix H). The comments, with one exception, were generally supportive and no significant adverse environmental impacts were identified during the comment period.

This final PEA and the resulting Finding of No Significant Impact (FNSI) will be released for public review and comment. Electronic copies of this document, the FNSI, and documents referenced in the final PEA will be made available on the world wide web. Finally, the public will be provided an opportunity to review and comment during the preparation of any subsequent EAs or EISs for this program.

2.0 DESCRIPTION OF THE PROPOSED ACTION

2.1 INTRODUCTION

The purpose of this section is to describe the JVAP so that the potential environmental impacts resulting from its implementation may be analyzed (see Section 4.0). This section, therefore, describes JVAP activities, their locations, the project scheduling, administration, and management. JVAP operations will be described along with the features designed to prevent or mitigate (lessen or alleviate) potential environmental impacts.

Section 2.4 describes how JVAP products (vaccines and toxoids) will proceed through the development and testing requirements necessary to achieve FDA licensure. This section also describes the authority and requirements of the FDA under which JVAP activities will operate to ensure that the products being developed and produced are safe and effective. Section 2.5 describes how various components of JVAP activities associated with development, production, storage, testing, and fielding of vaccines and toxoids will be conducted to address human health and safety and environmental considerations.

2.2 JVAP OBJECTIVES

A principal objective of the JVAP is to complete the development and testing required for FDA licensing of biological defense vaccines. Licensed vaccines will be produced and stockpiled in accordance with FDA requirements and in sufficient quantities to meet U.S. needs. The DoD has determined that biological defense vaccines are necessary for protecting service men and women assigned to high-threat areas and that all such vaccines should be licensed by the FDA (see Section 1.2). These vaccines will be developed for DoD-required product indications such as protecting soldiers against battlefield aerosol challenges with biological warfare (BW) agents (see Appendix A). Once these vaccines are licensed, the JVAP will enable their production in sufficient quantities to establish an initial stockpile as well as to perform the activities which are necessary to maintain vaccine licensure. It is not within the scope of the JVAP to provide the services associated with the DoD medical distribution chain, such as those actions and decisions leading up to and including the administration of vaccines to soldiers by trained medical personnel.

Listed in Table 2-1 are potential contract actions for accomplishing JVAP objectives for vaccine and toxoid development, production, storage, testing and fielding.

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TABLE 2-1. POTENTIAL CONTRACT ACTIONS FOR ACCOMPLISHING JVAP OBJECTIVES

Prime Systems Contract	
Basic Contract	
•	Integrated systems management to the development for licensure of Q-fever, vaccinia, and tularemia vaccines
•	Storage of biological defense vaccine stockpiles
•	Maintenance of current medical biological defense products
•	Performance of special studies in support of the JVAP
Contract Options	
•	Production of Q-fever vaccine
•	Production of vaccinia vaccine
•	Production of tularemia vaccine
•	Integrated systems management and development for licensure (15 options) and production (15 separate options) of the following additional vaccines
–	Botulinum monovalent serotype A
–	Botulinum monovalent serotype B
–	Botulinum monovalent serotype C
–	Botulinum monovalent serotype D
–	Botulinum monovalent serotype E
–	Botulinum monovalent serotype F
–	Botulinum monovalent serotype G
–	Botulinum polyvalent (serotypes A, B, E, F)
–	Ricin vaccine
–	Staphylococcal Enterotoxin B vaccine
–	Venezuelan Equine Encephalitis (VEE) vaccine
–	Combined Venezuelan, Eastern and Western Equine Encephalitis (VEE/EEE/WEE) vaccine
–	Brucellosis Multivalent vaccine
–	Improved Plague vaccine (alternative to existing product)
–	Improved Anthrax vaccine (alternative to existing product)
Contract Procurement of Existing FDA-licensed Anthrax Vaccine	
JVAP-related analytical and support contracts	

For additional information about the indications for these vaccines see Appendix C.

2.3 LOCATION AND FACILITIES

Vaccine research, development, and acquisition functions managed by the JPO BD are performed by DoD (predominately DA) activities, other Federal organizations, universities, and private sector industry. A prime systems contractor that has not yet been selected will serve to coordinate and implement the activities performed by many of these organizations for products listed in Section 2.2. Activities performed by U.S. government organizations, their associated contract support and analysis, as well as production of the currently licensed anthrax vaccine will continue and will not be performed by the prime systems contractor. For information about the process of selecting the JVAP prime systems contractor see Section 2.4.2.1.

The vaccines under development for the JPO BD are at various stages with respect to FDA licensure. Vaccine development and testing are currently conducted at several DA and private sector sites and are critical components of the process of obtaining FDA licensure. The JVAP prime systems contractor will develop and implement a plan to integrate the majority of these activities so that vaccines are developed, tested, licensed, manufactured, and stored and available for distribution when needed. The entities currently or recently performing research, development, and acquisition services for the JPO BD are shown in Table 2-2. For a description of Defense Acquisition Phases I, II, and III see Section 2.4.

TABLE 2-2. JVAP PARTICIPATING ORGANIZATIONS AND LOCATIONS

ORGANIZATION	LOCATION	FUNCTION
Department of Defense Locations		
Joint Program Office Biological Defense (JPO BD)	Falls Church, VA	Centralized management and program integration for Phases I, II, and III.
U.S. Army Medical Materiel Development Activity (USAMMDA)	Fort Detrick, Frederick, MD	Management and administration of assigned products for Phases I, II, and III.
U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)	Fort Detrick, Frederick, MD	JVAP monitored science and technology programs; assigned product development activities for Phases I and II.
U.S. Army Medical Research Acquisition Activity (USAMRAA)	Fort Detrick, Frederick, MD	Contacting Officer - contract solicitation, award, management activities for Phases I, II, and III.
Headquarters, U.S. Army Medical Research and Materiel Command (USAMRMC)	Fort Detrick, Frederick, MD	Regulatory compliance (e.g., safety, environmental, human use, and quality control) and legal assistance.
U.S. Army Medical Materiel Agency (USAMMA)	Fort Detrick, Frederick, MD	Medical logistics for Phases I, II, and III.

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ORGANIZATION	LOCATION	FUNCTION
Private Sector Locations		
JVAP Prime Systems Contractor To be determined	To be determined	Phases I, II, and III. JVAP integrated management; vaccine testing, production, storage, and distribution.
Battelle Memorial Institute, Medical Research and Evaluation Facility	W. Jefferson, OH	Phases I and II. Pilot lot production and efficacy testing.
Michigan Biologic Products Institute, [formerly called Michigan Department of Public Health (MDPH)]	Lansing, MI	Phases II and III. Manufacture, testing, storage, and delivery of FDA-licensed anthrax vaccine; blending of IND botulinum pentavalent (A-E) toxoid for testing.
The Salk Institute-Government Services Division (TSI-GSD)	Swiftwater, PA	Phases I and II. Pilot lot vaccine production, storage, testing and delivery of unlicensed vaccine candidates for preclinical and clinical testing.
Porton International	Porton Down, England	Phases I and II. Pilot lot production, storage, testing, and delivery of unlicensed vaccine (botulinum toxoid, multiple serotypes) candidates.
PerImmune, Inc.	Rockville, MD	Phase III. Production, storage, testing, and delivery of unlicensed horse antisera against botulinum toxins.

The JPO BD management and administrative activities are conducted in offices located in Skyline #3, Suite 1200, 5201 Leesburg Pike, Falls Church, Virginia. The JVAP Program Management Office (PMO) has an additional office performing management and administrative activities located at Fort Detrick, Maryland. Additionally, technical and analytical support services are provided to the JPO BD under contracts with Camber Corporation, Anser Corporation, and Science Applications International Corporation (SAIC). Staff from Camber work in the offices located in Falls Church and Fort Detrick as well as the Camber office located in Crystal City, Virginia. Staff from Anser work at the JPO BD Falls Church office. SAIC staff work in offices located at 1710 Goodridge Drive, McLean, Virginia and at 5340 Spectrum Drive, Suite N, Frederick, Maryland.

2.4 JVAP ACTIVITIES

2.4.1 Introduction

It is anticipated that JVAP activities will take place over a 10-year period. They will involve development, testing, production, stockpiling, and distribution of 18 different biological products, each of which will proceed independently through the licensure process. To facilitate the description of JVAP activities they have been organized according to DoD materiel life-cycle system management (Defense Acquisition) phases. JVAP activities include:

- **Administration and Management** — (see Section 2.4.2).
- **Defense Acquisition Phase I - Program Definition and Risk Reduction** — JVAP Phase I includes pilot lot production; nonclinical studies (safety, efficacy, potency, purity, modeling); preparation and filing of IND application with the FDA; and FDA Phase 1 and Phase 2 clinical studies (safety, potency, dose, and schedule) (see Section 2.4.3). Defense Acquisition Phase I concludes with Milestone II (see Figure 2.1).
- **Defense Acquisition Phase II - Engineering and Manufacturing Development** — JVAP Phase II activities include scale-up production; nonclinical studies (safety, efficacy, potency, purity, modeling); product standards; expanded Phase 2 clinical trials (safety, potency, dose and schedule); product and establishment license application preparation and submission; and FDA licensure (see Section 2.4.4). Defense Acquisition Phase II concludes with Milestone III (see Figure 2-1).
- **Defense Acquisition Phase III - Production, Fielding/Deployment, and Operational Support** — Phase III JVAP activities include FDA licensed vaccine production; lot release testing; final container fill/finish; storage and testing; shipment; disposal; post-marketing surveillance; and adverse event reporting (see Section 2.4.5).

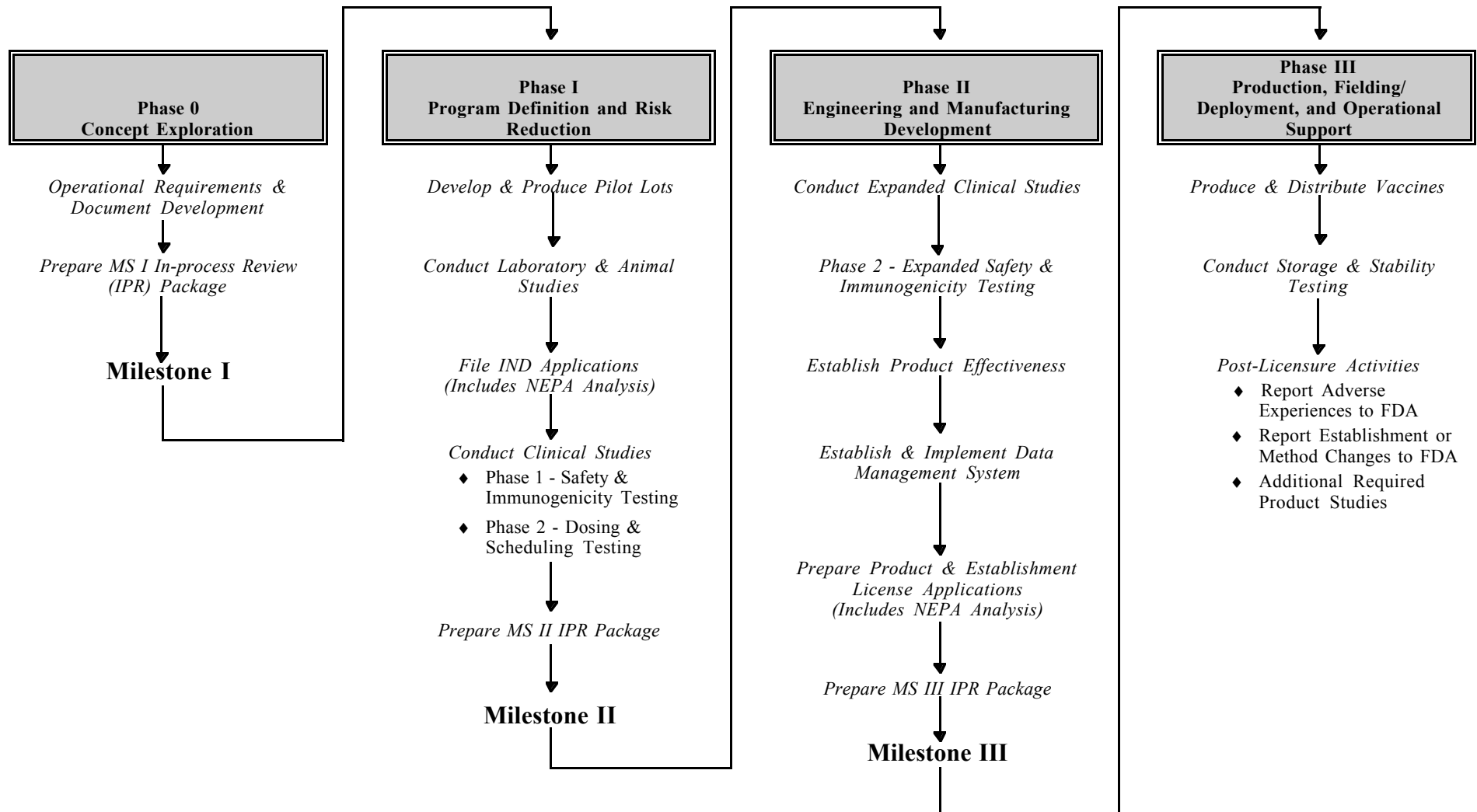
Figure 2.1 illustrates the interactions between milestones in the Defense Acquisition Phases described above and FDA-regulated phases of the development, testing, licensure, production, and storage of biological defense vaccines. It should be noted that all candidate biologic products (including both biological defense and infectious disease vaccines) must enter the FDA licensure process as INDs (see Section 2.4.3.3).

2.4.2 JVAP Administration and Management

The DoD will award a prime systems contract to a contractor who will devise and implement an integrated plan to achieve JVAP objectives for specific products listed in Section 2.2. Joint acquisition programs such as the JVAP are multi-service efforts for developing and procuring systems for providing the capability to address validated multi-service needs (e.g., biological defense vaccines). The prime contractor selected to manage the JVAP will perform the work required for obtaining and sustaining the product and establishment licenses required by the FDA for the products listed in Section 2.2.

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FIGURE 2-1. JVAP SCOPE



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The JVAP prime systems contract is anticipated to cover a 10-year period of performance with scheduling that considers that the vaccines in this program are at different stages of development with regards to FDA licensing. The planned implementation of the JVAP contract involves initial requirements and options. During the first 3 years, the contract calls for completing activities leading to the licensure of Q-fever, tularemia, and vaccinia vaccines. These products are at advanced stages and are likely candidates for licensure. Additional contractor requirements during this time period include providing storage for current biological defense vaccine stockpiles; maintaining current medical biological defense products; and performing required special studies on these products.

JVAP contract options for a product may be exercised when DoD determines that a product is ready for Phase I activities and when FDA licenses are obtained to initiate licensed production (see Sections 2.4.5). Contract options include the production of Q-fever, tularemia, and vaccinia vaccines (3 options) (Phase III activities, see Section 2.4.5). There are additional options for the integrated systems management and development for licensure (15 options) and production (15 separate options) of the following additional vaccines:

- Botulinum monovalent serotypes A through G
- Botulinum polyvalent (serotypes A, B, E, F)
- Ricin vaccine
- Staphylococcal Enterotoxin B vaccine
- Venezuelan Equine Encephalitis (VEE) vaccine
- Combined Venezuelan, Eastern, Western Equine Encephalitis (VEE/EEE/WEE) vaccine
- Brucellosis Multivalent vaccine (*Brucella abortus* and *Brucella melitensis*)
- Improved Plague vaccine (alternative to an existing, licensed product)
- Improved Anthrax vaccine (alternative to an existing, licensed product)

The JVAP prime systems contract will also require the storage, maintenance, and periodic testing of the vaccines, diagnostic reagents, seed stocks, and validated cell lines currently held at TSI-GSD. The prime systems contractor will be responsible for the processing, packaging, shipping, and disposal of these items.

The JVAP will be managed by the JPO BD. Under the direction of the JPM, the JPO BD provides centralized management and joint program integration for assigned DoD biological defense programs (e.g., the JVAP) related to biological agent detection and vaccines. The JPM serves as the principal advocate and single point of contact for all biological defense vaccine acquisition under this effort. The JPO oversees not only the prime systems contractor, but coordinates and directs all of the other entities (government and private sector) working for this program. The JPM is chartered by the Deputy Secretary of Defense and reports to the Under Secretary of Defense [Acquisition and Technology (Defense Acquisition Executive (DAE))], through the Army Acquisition Executive, with oversight by the Assistant to the Secretary of Defense (Nuclear, Chemical, and Biological Defense).

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JPO BD activities related to the JVAP are regulated by DoD Directive 5000.1, *Defense Acquisition*, dated March 15, 1996 and DoD Regulation 5000.2-R, *Mandatory Procedures for Major Defense Acquisition Programs and Major Automated Information System Acquisition Programs*, dated March 15, 1996. The JVAP is reviewed at least annually by the DAB.

The primary responsibility for directing, managing and administering the JVAP is undertaken by the Project Manager of the PMO. Among the responsibilities of this position is ensuring that the program fully complies with FDA regulations pertaining to the manufacture of vaccines (21 CFR) and Defense acquisition requirements of DoD Directive 5000.1 and DoD 5000.2R.

Significant management, regulatory affairs, and production challenges are associated with this program because of the number of different biological defense products included and the significant requirements of the FDA. JVAP contract terms specify that the contractor will be responsible to the FDA and serve as the license holder as well as the manufacturer for the products under development for the DoD. Implementation of this program will create a single integrator/manager that will develop and implement a detailed plan for vaccine life cycle management and use their scientific/regulatory expertise, management oversight, and physical resources to meet DoD requirements. The government and the contractor will establish Integrated Product Teams (IPTs) to work toward keeping program costs and risks down while improving the efficiency and capabilities of the JVAP.

The prime systems contractor will use currently available information and materials from the existing DoD biological defense program in creating and executing its integrated approach leading to FDA licensure and long term production and stockpiling of each vaccine. The prime systems contractor will provide all management services, personnel, facilities, equipment, materials (with the exception of seed stocks, certified culture, vaccines, and sera provided by the government), supplies, and documentation necessary to accomplish all specified tasks.

2.4.2.1 Contract Award and Administration

Selection of the JVAP contractor, and contract award, is being conducted through a competitive source selection process. This process is being administered by the USAMRAA with assistance from private sector contractors. This process of selecting the JVAP contractor is governed by the Federal Acquisition Regulations (FAR). These regulations direct contract award procedures, acquisition planning, and establish guidelines for competition. A RFP was made available to all interested parties on August 9, 1996 (DoD JVAP RFP, DAMD17-95-R-5020). An informational bidder's conference was held on August 29, 1996. The deadline for proposal submission was December 9, 1996. A decision regarding the JVAP prime systems contractor is expected to be made in 1997.

The government requested that proposals submitted demonstrate that the bidder has the necessary technical, management, and financial capabilities to perform the required activities. The award of contracts of this nature is not determined solely on the basis of price. The

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government does not have to select the lowest priced, acceptable offer, but may select a higher-priced offer that represents the “best value” to the government. The government may award a contract to the entity whose proposal best conforms to the government’s requirements and who is deemed responsible.

The entities competing for the JVAP contract must supply a great deal of information for evaluation including information about safety and environmental consideration. For example, bidders are requested to conduct an Environmental and Safety Analysis, to include safety inspections and the development of reporting memoranda. In addition, the bidders must submit a Memorandum for Environmental and Safety Analysis in which they provide evidence that facilities, safety equipment, laboratory environmental controls, and operating procedures are in place and that the contractor has both an established program and the resources to conduct research safely and in an environmentally responsible manner. A contractor’s plan must be in place on the date of contract award. Bidders must certify whether they are, or are not, in compliance with applicable national, state, and local environmental and safety laws and regulations. If the contractor is not in compliance, details and evidence of approved mitigation measures must be submitted. Contract provisions require that the government be notified if the offeror has been informed by the EPA that it (or other facility under consideration for performance of the contract) is listed, or under consideration to be listed, on the EPA List of Violating Facilities.

2.4.2.2 The Role of the U.S. Food and Drug Administration

The development, production, storage, testing, and fielding of the vaccines listed above will require considerable coordination with the FDA during the execution of this program. These activities are regulated and enforced by the FDA as the federal agency responsible for protecting the human health from impure and unsafe foods, drugs, cosmetics, and medical devices. The FDA is an office of the U.S. Department of Health and Human Services (DHHS). Within the FDA, the Center for Biologics Evaluation and Research (CBER) administers the regulation of biological products under the applicable provisions of the U.S. Food, Drug, and Cosmetics Act. CBER’s authority extends to inspecting manufacturer’s facilities for compliance with standards; testing products and establishing product standards; and approving the licensing of manufacturers to produce biological products. FDA regulations governing biological products are found in Title 21 of the Code of Federal Regulations (21 CFR).

In addition to its role in regulating and enforcing laws related to the development, testing, and production of vaccines, the FDA, as a federal agency, also has responsibility for analyzing the environmental impacts of the products that it licenses and operations it regulates. The FDA’s regulations implementing NEPA (see Sections 1.1; 2.4.3.3; 2.4.4.5; and 4.3) are found in 21 CFR 25 (Environmental Impact Considerations).

2.4.3 Defense Acquisition Phase I (Program Definition and Risk Reduction)

2.4.3.1 Development and Production of Pilot Lots of JVAP Vaccines

In Phase I, a pilot lot of the biological product (vaccine or toxoid) is produced for use in a variety of studies. The location of pilot lot production of vaccines will vary depending on the product. Pilot lot production of JVAP vaccine candidates has taken place at Porton International and TSI-GSD. Studies that are conducted on pilot lots include those for safety, purity, stability, immunogenicity (ability of the vaccine to effect an immune response), dosing (what quantity is needed for the desired effect), scheduling (how often are doses necessary), and related studies needed to support product development and licensure requirements. The production of pilot lots of vaccines is regulated by the FDA under the *Current Good Manufacturing Practices (cGMP)* (21 CFR Parts 210-226 and 600-660). FDA regulations address manufacturing issues including the qualifications of the organization and personnel performing the work; facilities and equipment used; production processes and process controls; use of animals; filling procedures, containers, and closures; labeling and storage; record keeping; sample maintenance; and pilot lot acceptance testing and shipment.

2.4.3.2 JVAP Laboratory and Animal Studies

Using vaccine produced in the pilot lots described above, preclinical (non-human) studies are used to demonstrate that a vaccine or toxoid should be safe for use in humans and effective for its intended purpose. Laboratory studies and animal studies of JVAP vaccine candidates have taken place at USAMRIID, Porton, and TSI-GSD. Such studies also develop and validate (confirm) markers (measurable cells or chemicals) that can later be used to predict product potency and efficacy in subsequent human trials and for defining product standards. The FDA *Good Laboratory Practices (GLP) for Preclinical Studies* regulates the conduct of these studies. GLP regulations prescribe the laboratory practices; facilities and equipment; qualifications of organizations and personnel; experimental protocols and conduct of laboratory studies; record keeping and reporting; sample maintenance; and the testing and controls required for product safety (21 CFR Part 58). For information regarding laboratory safety see Section 2.5. For information regarding the use of animals in experiments see Section 2.6.

2.4.3.3 Filing Investigational New Drug Applications

When sufficient information has been gathered to demonstrate that a vaccine will likely be safe and effective for its intended use in humans, application may be made to the FDA for the authorization to study the vaccine in humans. In the case of the JVAP, the selected prime systems contractor will seek such authorization by filing an IND with CBER (21 CFR Part 312). The FDA defines an IND as any drug not approved for marketing and any drug used for treatment other than that identified in the approved labeling. Biological defense vaccines which are currently authorized by the FDA as INDs include tularemia, Q-fever, VEE, EEE, and WEE vaccines and some botulinum serotype toxoids.

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It is under the IND that all studies and tests for developing data to support the Product License Application (PLA) and the Establishment License Application (ELA) are conducted. The FDA must review each JVAP IND application. In reviewing INDs, the FDA's objectives are to assure the safety and rights of human subjects and to ensure the scientific quality of information on an investigational product will demonstrate whether the product is both safe and effective for its intended purpose. The FDA must review and accept an IND application before a product can be shipped across state lines or be administered to a human subject. JVAP vaccines may be shipped across state lines and clinical investigations may be initiated 30 days after receipt of an IND by the FDA, and absent notification by the FDA that clinical trials may not be initiated, or having received specific permission by the FDA to proceed.

The IND process must be completed for each vaccine candidate and is ongoing and dynamic. The initial IND application submitted for a product must focus on the general investigational plan and the protocols (detailed plans) for specific human studies. The initial IND submission provides the rationale for the design of clinical trials, protocols for specific human studies, and administrative information about the sponsor, investigator, and the performing organization. Amendments to an IND are filed with the FDA at major milestones in product development, at the request of the FDA, and in fulfillment of the requirement for annual IND reports. Investigational New Drug amendments provide information obtained as the result of animal or human studies. Annual reports to the IND file contain information pertaining to the status of studies that are being conducted under the IND and update the general investigational plan.

As previously discussed, the FDA has obligations under NEPA to analyze the environmental impacts of its actions, such as approving a product. The potential environmental impact of each biological product is assessed at the time application for licensure is submitted to the FDA. The FDA requires that all applications for INDs and product licenses be accompanied by an EA, EIS, or claim of categorical exclusion. The format and requirements for these submittals are located in 21 CFR 25 (see Section 4.3).

2.4.3.4 Conduct of Clinical Trials for JVAP Vaccines

After a JVAP vaccine candidate achieves IND status, clinical investigations may proceed. A clinical investigation involves testing in which a biological product is given to one or more human subjects. For these purposes *testing* is defined as the use of a drug or biological product other than one marketed for use in the course of medical practice. Clinical trials are conducted in phases referred to as *Phase 1* (safety and immunogenicity testing) and *Phase 2* (dosing and scheduling testing). Phase 1 clinical trials are the first introduction of an investigational product into humans. Phase 1 investigations generally involve 20-50 human volunteer subjects and are used to determine human reaction to a product. In addition to obtaining initial safety information, data are collected to assess a product's immunogenicity (ability to effect an immune response). Activities conducted in Phase 1 investigations are regulated by the FDA (21 CFR Part 312) as well as rules for the use of human subjects (see Section 2.7).

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Data obtained from Phase 1 clinical studies lead to an estimation of the adequacy of the dose of product for eliciting an immune response. Such assessment determines whether additional studies are required to further determine adequate dosages during Phase 2 studies. Phase 2 testing includes determination of the immunization schedule (e.g., one dose of vaccine every month for 2 months). Phase 2 studies are generally conducted in clinical settings with a larger subject population (approximately 50 subjects). Activities conducted in Phase 2 investigations are regulated by the FDA (21 CFR Part 312) as well as rules for the use of human subjects in research (see Section 2.7).

The FDA's review of the IND application for Phase 2 studies focuses on ensuring that the quality of the scientific evaluation is adequate for determining product effectiveness and safety and the likelihood that the investigations will yield data capable of meeting the legal standards for marketing approval.

2.4.4 Defense Acquisition Phase II

Tularemia, Q-fever, and vaccinia vaccines are currently in Phase II at USAMRIID and TSI-GSD. Prior to the commencement of this phase for a given product, the JPM reviews the data developed under the IND and will review any concerns which have been expressed by the FDA. Normally during Defense Acquisition Phase II, technology developments continue and refinements are made to incorporate test results and technology upgrades. In the case of FDA-regulated biological products, however, the product under development has already been well characterized and preclinical studies have been completed by this stage. FDA regulations preclude changes to the product and require that preclinical studies must be repeated if changes are to be made in the product or the methods in which the product is to be made. Accordingly, vaccine development under the JVAP will follow the FDA-regulated steps.

2.4.4.1 Production Scale-Up Activities

Production scale-up activities commence after a vaccine candidate has been evaluated under Defense Acquisition Phase I components, according to the requirements of the FDA, and upon approval of the JPM. Production scale-up involves demonstrating that the product can be reproducibly manufactured, by production of three to five lots, within the limits of very specific, nonclinical and clinical, product standards that are required and accepted by the FDA. A lot is a specific quantity of material manufactured under identical conditions and assigned an identifying lot number. The production lots of JVAP IND vaccines resulting from scale-up runs will be used to complete the additional clinical and nonclinical investigations needed to support application for licensure. Production methodology is a critical element of the licensure process with impacts on facility requirements and the criteria that the FDA will use to license the final product. Production scale up is regulated by the FDA (21 CFR Parts 210-226 and Parts 600-660). Discussion of environmental protection and human health and safety considerations in production is located in Section 2.5.

2.4.4.2 Expanded Clinical Studies

Phase 2 (expanded safety and immunogenicity testing) studies are conducted to gather additional safety and human response data on an IND product. Such studies are generally conducted in controlled field settings such as a university medical center with the capability to closely monitor 50 to 150 volunteers for each of the three to five product lots manufactured during the production scale-up activities. The data obtained from Phase 2 studies are used to validate the dosage and scheduling required for the IND and contribute to the overall knowledge about product safety and immune response collected during earlier study of the IND. Information gained during Phase 2 expanded safety and immunogenicity investigations is also used to confirm the adequacy of product standards; to predict human safety and immunogenicity; and to extrapolate animal effectiveness test data for product effectiveness in humans. Clinical data collected during this phase are related to studies conducted earlier in the development and are used to predict that the product will be safe and effective when used in the target population (e.g., the soldier). Phase 2 clinical investigations are regulated by the FDA (21 CFR Part 312) as well as the rules which govern the use of human subjects in experimentation (see Section 2.7).

2.4.4.3 Establishing Product Effectiveness

The FDA regulates efficacy testing required for product licensure (21 CFR Parts 312 and 600, § 601.40-§ 601.44). A significant difficulty associated with obtaining FDA licensure for the biological defense vaccines and toxoids listed in Section 2.2 is the inability to demonstrate product effectiveness through the conduct of large-scale clinical trials. The FDA normally requires that large-scale clinical trials be conducted using hundreds to thousands of volunteers to demonstrate that an investigational product is both safe and effective for its intended purpose (i.e., a vaccine is effective in preventing disease in an exposed person). Conducting such trials with biological defense vaccines and toxoids would require that human subjects be intentionally exposed to biological warfare agents by the most probable route of exposure, usually aerosol. For both ethical and statutory reasons, such human efficacy testing is neither possible nor planned.

The efficacy of the biological defense vaccines and toxoids developed within the JVAP will be tested and evaluated by alternate methods, reviewed and accepted by the FDA for each vaccine and toxoid candidate. The FDA has the authority (21 CFR § 601.41) to approve a license application based upon a “...*surrogate endpoint or on an effect on a clinical endpoint other than survival or irreversible morbidity [illness].*” Approvals under this section “...*will be subject to the requirement that the applicant study the biological product further, to verify and describe its clinical benefit, where there is uncertainty as to the relation of the surrogate endpoint to clinical benefit, or of the observed clinical benefit to ultimate outcome.*” Such methods may include the use of animal models. Animal models have been accepted and used for demonstrating the efficacy of other FDA-licensed vaccines in humans including those for rabies and tetanus. For further discussion of the use of animals within the JVAP see Section 2.6.

2.4.4.4 Data Management System Initialization and Implementation

A data management system will be used for each biological defense product under development. These systems will establish and maintain product information in support of all FDA reporting and subsequent filing requirements. The data maintained will include those nonclinical data to support IND submission; nonclinical and clinical data developed under the IND and submitted with the PLA/ELA; product test data, as well as manufacturing information on each lot of product; product storage and distribution data; and data obtained after a vaccine is in use, including the required reporting of adverse experiences. Data management activities are regulated by FDA (21 CFR Part 312 and § 600.80 - § 600.81). For additional information about the reporting of adverse events associated with JVAP products see Section 2.5.7.3.

In addition to the information maintained in support of FDA requirements, information will be maintained on the individuals who are administered JVAP products. This will provide a means for identification of individuals receiving medical biological defense products and allow for study of potential long-term or delayed effects of product administration.

2.4.4.5 Product and Establishment License Applications

The FDA has regulatory authority over biological products as well as the establishments in which they are made. Products and all establishment locations at which products are made must be licensed by the FDA. The JVAP prime systems contractor will submit both a Product License Application (PLA) and an Establishment License Application (ELA) to the FDA, Director, CBER for each product. In anticipation of licensure, a draft Defense Acquisition Milestone III (MS III) In-Process Review (IPR) package will be prepared. The MS III IPR will be held only after licensure of the product by the FDA, and includes reassessing the biological warfare threat, the requirement, and the proposed use of the product, and obtains approval to begin production. If FDA has expressed any specific issues with regard to the applications for licensure, these issues will be presented at the time of the IPR.

The PLA must include the detailed procedure for making the product and all of the nonclinical laboratory and clinical data developed under the IND to demonstrate that the product meets FDA standards. The ELA must include detailed information on the facility, equipment, and procedures used throughout the entire process of manufacturing the product. The information submitted must include a description of the procedures used to validate equipment performance; procedures used to control the manufacturing process including final container filling, labeling and storage; and information on animal use, storage of manufacturing records, and computer systems. The FDA regulations pertaining to the PLA and ELA are located in 21 CFR Parts 314, 600, and 601.

In addition to the FDA requirements discussed above, each PLA submitted to the FDA must contain information pertaining to the potential environmental impacts associated with the

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manufacture and use of the product. This requirement is part of the FDA's legal requirement to examine the potential environmental consequences of FDA's actions, that is, approval for the manufacture of a drug or biological product such as a vaccine. The initial assessment of the potential for environmental consequences of the proposed action (the production and use of a biological defense vaccine) will require either an EA or EIS or both, or will be categorically excluded. If an EA is required, it will result in the publication of either a Finding of No Significant Impact (FONSI) or, if the action is found to have potential significant environmental impacts, a Notice of Intent (NOI) to prepare an EIS. Both the FONSI and the NOI are made available to the public. The responsibility to provide the analysis of the potential environmental impacts associated with a product is placed by the FDA upon the license applicant, in this case, the JVAP prime systems contractor. The FDA regulations pertaining to NEPA are located in 21 CFR Part 25. For additional information about the requirements for environmental analysis see Section 4.3.

The FDA issues a single establishment license for all locations that manufacture a specific product. An establishment license is issued only after establishments are inspected and found to be in compliance with FDA standards. During the establishment inspection, the product to be licensed must be available for inspection during all phases of the manufacturing process. Product lot samples are submitted along with the PLA, and the product license may be issued only after the product has been examined and found to be in compliance with FDA product standards.

Once a JVAP vaccine has been licensed by the FDA, the license will remain valid until either suspended or revoked by the FDA. The reasons for which the FDA may revoke a license once it is issued include: (1) revocation is requested by the manufacturer after giving notice of the intention to discontinue manufacturing the product or all products; (2) inability of FDA staff to gain access to an establishment for inspection; (3) finding that the product is not safe or effective; (4) manufacturing has been discontinued or is at such a low rate that effective inspections and evaluations cannot be made; (5) the production establishment or the product fails to conform to FDA standards to ensure safety, purity and potency of the product; or (6) the establishment or manufacturing methods have been changed so that it is necessary to re-establish product standards. The Commissioner of the FDA may suspend a license pending review actions related to license revocation and such actions may include hearings. If a license is revoked, notice of the revocation and the reasons for it will be published in the Federal Register. If a license is suspended or revoked for noncompliance reasons, it may be reinstated when the product and establishment are brought back into compliance with FDA standards.

2.4.5 Defense Acquisition Phase III

The JVAP prime systems contractor will manage the production of an initial stockpile of at least 300,000 troop equivalent doses for each licensed vaccine. (A troop equivalent dose is defined as the number of immunizations required for the primary immunization of a single individual.)

2.4.5.1 Production and Distribution of JVAP Vaccines

After product and establishment licenses are issued, and after receiving DoD approval to begin, the JVAP prime systems contractor may initiate FDA-licensed vaccine production and distribution activities. Production must follow the procedures specified in the PLA for each product, and the facility and equipment must be operated as specified in the ELA and in continuous compliance with cGMP. Prior to release for distribution, however, each lot of a biological product must be tested and must meet the established product-specific standards that include potency, sterility, purity, identity, and content of constituent materials. A product lot may only be released for distribution after approval for lot release has been obtained from the Director, CBER. In order to continuously verify product potency, the FDA specifies the number of lots to be subjected to stability testing at prescribed intervals up to the expiration date. Lot samples, to include the final container, must be retained for at least 1 year following the lot expiration date, and all records pertaining to the production, storage and distribution of the product must also be retained for at least 1 year.

The FDA has regulatory authority for ensuring that biological products are safe and effective for their intended purpose and that products are only used for the purpose for which they were licensed. According to FDA regulations, any modifications to the manufacturing process (e.g., implementation of new technology to improve product yield) require that the clinical portion of any supporting studies be conducted under an IND (Phase 1) and any resultant product and manufacturing establishment be reviewed under what are essentially new license applications. Changes to a biological product's dose and immunization schedule require that the clinical results supporting this change be obtained under an IND; however, a supplement to the existing PLA may be allowed. If no manufacturing changes have been made, a supplement to the ELA may not be required.

2.4.5.2 Storage and Stability Testing of JVAP Vaccines

The FDA regulates the storage and stability testing of JVAP vaccines (21 CFR Parts 211 and 610) and requires that written procedures describing the warehousing of products be established and followed. Required procedures include quarantine of the product until lot release criteria are reviewed by FDA, and storage of the product under appropriate conditions of temperature, humidity, and light so that established product standards are maintained. The JVAP prime systems contractor must develop written procedures describing product distribution; procedures for ensuring that the oldest approved product stock is distributed first; and procedures for ensuring that the distribution of each product lot can be readily determined to facilitate recall if necessary.

The FDA requires that written programs be established for testing the stability of biological products. The results of such stability testing will be used to determine how to appropriately store each vaccine and toxoid and to determine product expiration dates. The JVAP prime systems contractor must (a) conduct stability testing as part of a continuous program;

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(b) maintain information about the functions and training of each person involved in testing procedures, from the responsible head down to the animal caretaker; (c) maintain and control laboratory animals used in testing in a manner that ensures their suitability for intended use, and maintain adequate records about their use; (d) must reserve product samples for 1 year after the expiration date; and (e) maintain production, control, and distribution records for at least 1 year after the expiration date of the batch. The transportation and disposal of outdated, rejected or excess vaccines are discussed in Section 2.5.4.5.

2.4.5.3 Post-Licensure Activities

Reporting Adverse Experiences to the FDA

Following approval of a product license by the FDA, the JVAP prime systems contractor must provide the FDA with reports of adverse experiences associated with the use of that product as required by 21 CFR § 600.80. Reports of adverse experiences will be submitted to the JVAP prime systems contractor (the license holder) by health care providers (e.g., physicians, nurses, pharmacists). FDA regulations specify the manner in which various adverse experiences must be reported. In the case of licensed products of the JVAP, the prime systems contractor must report in one of the following ways:

- Adverse events which are serious and unexpected must be reported to the FDA within 15 working days after the manufacturer is notified of the event. This 15-day alert reporting also applies to observation of a significant increase in frequency of an adverse event which is serious but expected. Such frequency determinations must be made on, at least, a quarterly schedule. This 15-day alert reporting requirement exists for the duration of license approval.
- For each of the first 3 years following licensure, the licensee (JVAP prime systems contractor) must file at least four reports which include all adverse events which do not qualify for inclusion in the 15-day reports because they do not meet the criteria of being serious or unexpected. The FDA may extend this 3-year period at its discretion.
- For the duration of the product license, a report listing all adverse reactions reported to the licensee must be sent to the FDA annually.

Reporting Establishment or Method Changes to the FDA

The FDA has ongoing regulatory control over the products and establishments it licenses (21 CFR § 601.12). The JVAP prime systems contractor must report any important pending changes relating to the establishment(s) where the vaccine is manufactured. Changes that must be reported for FDA review but do not require FDA approval before enactment are changes in location within the establishment, equipment, management and responsible personnel. Any proposed changes in the methods used to manufacture or label a vaccine or toxoid cannot be made until reviewed and accepted by the Director, CBER.

Additional Required Product Studies

It is anticipated that most, if not all, of the JVAP vaccines will be subject to post-licensure requirements. It is within the authority of the FDA to require that a structured clinical research program be continued following the licensure of a vaccine as a condition of the granting of the license (21 CFR § 601.26[f]). Licensure may also be conditional upon collecting additional information concerning the efficacy of the vaccine. The JVAP prime systems contractor must submit a written statement to the FDA demonstrating that the studies required as a condition of licensure are adequate and appropriate to resolve any remaining questions about the product in question. Failure to provide such a statement and commitment to pursue such studies results in license revocation. The licensee is required to report on all such studies biannually (January and July) or risk losing FDA licensure.

2.5 ENVIRONMENTAL AND SAFETY POLICIES AND PROCEDURES

2.5.1 Introduction

The following sections describe the policies and procedures under which the Defense Acquisition Phase I, II, and III activities described in Section 2.4 must be conducted to ensure environmental protection and the health and safety of workers and the public. The incorporation of accepted safety practices and procedures into all aspects of implementation of the proposed action ensures product safety and effectiveness, environmental integrity, and the health and safety of workers and the public and is required by an array of Federal, DoD, DA, state, and local laws, regulations and policy.

2.5.2 General Safety Requirements

Defense Acquisition Phase I, II, and III activities previously described have been and are likely to continue to be carried out at several known facilities throughout the U.S., a facility in Great Britain, and at additional sites yet undetermined pending contract awards. Some of these sites are Federal (DoD) and some are in the private sector (see Table 2-2). All sites of program execution, regardless of whether they are Federal facilities or in the private sector, must adhere to standards of operations, including organizational and management standards of practice, which promote laboratory safety and which incorporate all regulatory requirements of Federal, state, and local governments.

All sites of program execution (including private laboratories) must comply with the DoD, DA, Federal, state, and local laws and regulations pertaining to the safe use, handling, and disposal of etiologic agents and other potentially hazardous materials such as chemicals and radioisotopes. An etiologic agent is defined as any viable viral or microbial agent or its toxin which causes or may cause human disease. In addition, compliance with all laws and regulations pertaining to the use of animals and humans in research will be required. In some cases, regulations will overlap

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and/or state or local jurisdictional requirements will be more stringent than those of the DA or Federal government. In such cases, work will be conducted under the more stringent regulation.

Contractual agreements between the JPO BD and its contractors will detail compliance with all applicable Federal and state laws, codes, ordinances, and regulations (including obtaining licenses and permits). These agreements will require the submittal of documentation and certifications concerning numerous aspects of safety and protection of human health and the environment. Demonstrated understanding of and compliance with health, safety, and environmental requirements are factors by which entities considered as possible sites for the JVAP will be evaluated. All entities under consideration for biological defense vaccine production work have been or will be required to submit detailed documentation describing the implementation of their occupational safety and health programs and have or will certify to the JPO whether they are, or are not, in compliance with the Federal, state, and local environmental and safety laws and regulations applicable to their operation.

All activities of a hazardous nature performed by either civilian or military personnel at DA work sites are governed by the *Army Safety Program* (AR 385-10) which implements by reference all applicable Federal, state, local, DoD, and DA requirements. This comprehensive safety regulation defines safety management and responsibility, personnel training, personal protective equipment and clothing, waste-handling procedures, inspections, spill and emergency procedures, hazard communication, and other elements impacting on safety. The Army Safety Program for all aspects of the Biological Defense Program is established in AR 385-69, *Biological Defense Safety Program* (32 CFR Parts 626, 627). Contractor compliance with these and related requirements is defined and implemented through contract clauses.

Additional safety requirements include compliance with guidelines for the design, construction, and maintenance of safe laboratory facilities. These guidelines include the codes and standards of the National Fire Protection Association (NFPA), the Occupational Safety and Health Administration (OSHA), the National Electrical Code (NEC), and the Environmental Protection Agency (EPA). Additional requirements are found in DoD Instruction 6055.1 (*DoD Occupational Safety and Health Program*) and AR 420-90 (*Fire Prevention and Protection*). All program sites will be required to submit information to the Army about the existence of relevant Federal, state, or local environmental documents; assessments; reports; and/or building use or construction permits relating to conduct of the proposed action. Contract clauses will require obtaining and adherence to permits on water, air, and disposal.

All program sites must have written policies which detail their institutional safety programs and rules by which these programs function. Potential contractors have been and will be required to provide evidence of the management and operation of their institutional safety programs including information about the structure and function of safety committees. They must submit documents which describe and codify their safety program; and which detail other program elements including their biological safety program, chemical safety program, and radiological safety program.

2.5.3 Facility Safety and Emergency Coordination

All JVAP facilities engaged in work for the JPO BD must prepare and submit information about their operations and physical facilities to the DA for evaluation. The information required will include descriptions of laboratory floor plans for research areas used; drawings indicating the location of emergency exits and evacuation routes; the location and availability of emergency fire equipment systems (sprinkler, halon systems); and the location of biological safety cabinets, fume hoods, and other equipment or engineering controls.

Communication with local emergency services (police, fire, health) is required and defined by AR 385-10 and AR 385-69. Contractors must provide the JPO BD with plans for communication and coordination with local emergency authorities regarding the potentially hazardous materials used in the laboratory, including etiologic agents. This information is to include the dates of agreements and renewal. Annual documentation of agreements between the contractor and local emergency service providers is a requirement of JVAP-funded work.

2.5.4 Use, Handling, and Disposal of Etiologic Agents

Safety in the production of biologic products concerns the purity and effectiveness of product (regulated by the FDA), as well as protecting the health and safety of the production workers, the public, and the environment. Defense Acquisition Phases I, II, and III require the use of etiologic agents and therefore the use of special containment equipment and procedures to prevent workers, the environment, or the public from exposure (see Section 2.5.4.1).

AR 385-69 provides DA policy on biological safety involving biological defense etiologic agents. AR 385-69 implements DA and DoD policy statements, and other applicable regulations. It prescribes DA safety policy, responsibilities and procedures for biological defense research, development, and acquisition (RDA) operations. AR 385-69 also defines the safety rules that apply to contractor operations, and requirements for contractor review, and mandates the preparation of written procedures for reviewing a contractor's ability to safely perform biological defense program work involving etiologic agents.

Etiologic wastes and materials with the potential for causing disease must be inactivated by physical (autoclave) or chemical means prior to removal from production suites or laboratory areas. All wastewater originating from laboratories and production suites and containing potentially infectious materials will be decontaminated on site by physical or chemical in accordance with Federal, DA, DoD, state and local regulations. Regulated medical wastes (e.g., sharps, waste vaccine, waste cultures), animal carcasses and bedding must be disposed of in accordance with applicable Federal, DA, DoD, state, and local regulations. These rules specify the labeling, packaging, tracking, transport, and disposal of wastes.

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Prior to the commencement of activities, facilities must provide the JPO BD with documentation regarding their waste management programs including agreements for connection to municipal sewer systems; agreements for connection to private or municipal incinerators; and specific provisions for dealing with laboratory effluent or wastes.

2.5.4.1 Biological Safety Levels (Biocontainment)

Among its other provisions, AR 385-69 *mandates* implementation of the laboratory biosafety guidelines prepared by the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) on laboratory biosafety (CDC/NIH, 1993). This requirement applies to work performed by both government (e.g., DA) and private sector entities.

The CDC/NIH guidelines recommend the levels of laboratory practices and techniques, facilities, and equipment necessary to contain infectious organisms of varying degrees of pathogenicity and virulence, and their products. The CDC/NIH guidelines describe four biosafety levels (BL) at which it is recommended that laboratory operations with certain infectious agents and/or their toxins be conducted. Biosafety levels describe the minimum combinations of techniques, safety equipment, and laboratory facilities recommended to control and contain the potential hazards associated with the use of etiologic agents. Animal biosafety levels (ABLs) describe the combinations of practices, safety equipment, and containment recommended for work involving vertebrate animals infected with agents known or believed to cause infections in humans.

Biosafety level 1 (BL-1) practices, safety equipment, and facilities are appropriate for work which involves defined and characterized strains of viable microorganisms not known to cause disease in healthy adult humans. Biosafety level 2 (BL-2) practices, safety equipment, and facilities are appropriate for performing work with the broad spectrum of indigenous moderate-risk agents present in the community and associated with human disease of varying severity. Work with indigenous or exotic agents that have serious or lethal consequences if inhaled requires BL-3 containment. Biosafety level 4 (BL-4) practices, safety equipment, and facilities are required for work with dangerous and exotic agents which pose a high individual risk of life-threatening disease. Under these guidelines, the laboratory director is responsible for determining the appropriate BL based upon “the virulence, pathogenicity, biological stability, route of spread, and communicability of the agent; the nature or function of the laboratory; the procedures and manipulations involving the agent; the endemicity (natural occurrence in the local community) of the agent; and the availability of effective vaccines or therapeutic measures” (CDC/NIH, 1993). The CDC/NIH guidelines include agent summary statements which provide guidance for the selection of appropriate BLs and specific information on laboratory hazards associated with various agents (CDC/NIH, 1993).

In assigning a BL, the laboratory director must take into consideration such factors as the volume and concentration of the agent as well as activities which by their nature may be intrinsically more hazardous (e.g., manipulations likely to introduce etiologic agents into the air). The

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CDC/NIH Guidelines discuss production quantities of etiologic agents and the determination of appropriate BLs as follows:

“‘Production quantities’ refers to large volumes or concentrations of infectious agents considerably in excess of those typically used for identification and typing activities. Propagation and concentration of infectious agents as occurs in large-scale fermentation, antigen and vaccine production, and a variety of other commercial and research activities, clearly deal with significant masses of infectious agents that are reasonably considered ‘production quantities.’ However, in terms of potentially increased risk as a function of the mass of infectious agents, it is not possible to define ‘production quantities’ in finite volumes or concentrations for any given agent. Therefore, the laboratory director must make an assessment of the activities conducted and selected practices, containment equipment, and facilities appropriate to the risk, irrespective of the volume or concentration of agent involved” (CDC/NIH, 1993).”

All work involving biological defense etiologic agents is monitored and inspected in accordance with AR 385-69. At a minimum, pre-award on-site inspections are performed for work involving BL-3 and BL-4 containment and pre-operational inspections of work in which major changes in procedures, facilities, or equipment are made after the pre-award survey. Subsequent to contract award, inspections of BL-3 and BL-4 facilities, equipment, and operations are performed annually and semiannually, respectively. AR 385-69 specifies that these inspections be conducted by safety and occupational health professionals trained in biological defense RDA operational safety requirements. Inspections of BL-1 and BL-2 biological defense contractors are conducted prior to contract award and annually thereafter by safety and occupational health professionals or contracting agency representatives trained in biological safety inspection techniques. DA PAM 385-69 provides a checklist for performing these inspections. It is not anticipated that JVAP activities will require the use of BL-4 containment. Any proposed future work requiring BL-4 containment will require additional NEPA analysis. Should JVAP activities require BL-3 containment in any location other than existing BL-3 facilities, additional NEPA analysis will also be required.

2.5.4.2 Recombinant DNA

Safety practices for work involving recombinant DNA are described in *Guidelines for Research Involving Recombinant DNA Molecules* (Federal Register, May 7, 1986). DoD policy, as well as AR 385-69 and its associated technical guidance (DA PAM 385-69), mandate compliance with the NIH guidelines for work with recombinant DNA. The NIH guidelines require that an institutional biosafety committee be established to review all protocols and provide oversight for all activities involving recombinant DNA. This committee is generally composed of scientists with expertise in recombinant DNA as well as members of the local community.

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The NIH guidelines identify specific containment practices for large-scale (LS) fermentation (greater than 10 liters of culture) involving organisms containing recombinant DNA molecules. These guidelines require that large-scale operations apply physical containment at the same BL as if they were conducted at the laboratory level, except that quantities in excess of 10 liters must be handled in closed-systems and exhaust gases must be filtered through a high efficiency particulate air (HEPA) filter.

2.5.4.3 Transportation of Etiologic Agents

Special rules apply to the shipment of etiologic agents and to biological defense etiologic agents. The packaging, labeling, shipping, and transport of etiologic agents are regulated by 42 CFR Part 72 (Interstate Shipment of Etiologic Agents), 49 CFR Parts 172 and 173 [Department of Transportation (DOT) Regulations], 9 CFR Part 122 (U.S. Department of Agriculture Restricted Animal Pathogens), and International Air Transport Associated Regulations. Etiologic agents used in the biological defense program must be packed, labeled, marked, prepared, and shipped in accordance with AR 385-69 and all applicable Federal, state and local regulations. Private couriers, and not the U.S. Postal Service, are used for transport of etiologic agents used in the biological defense program. BL-4 agents or USDA-restricted animal pathogens must be accompanied by a courier or other responsible party assigned to monitor shipment and final receipt. Audit trails of all etiologic agent shipments are maintained for 3 years.

In addition to regulations which govern the shipment of etiologic agents, special rules apply as well to the transport of materials regulated by the FDA (21 CFR 312 § 601.20).

2.5.4.4 Regulated Medical Waste

The handling and disposal of medical wastes are regulated by Federal, DA, state, and local laws and regulations. Generally, regulated medical waste (RMW) is defined as any waste material generated during diagnosis, treatment, immunization or research involving animals or humans and includes waste material generated in the production or testing of biologicals (49 CFR Parts 172-179, Transportation of Hazardous Waste). Procedures used to treat, handle, and dispose of RMW are designed to minimize potential health risks to the individuals and the community. Cultures and stocks, pathological wastes, animal wastes, blood and blood products, and used and unused sharps are the classes of RMW described in 49 CFR Parts 172-179.

The OSHA and the DA also regulate the management and disposal of used sharps (AR 40-5,11-7c (e)). Sharps are defined as used or unused waste needles, syringes, pipettes, and other materials which pose a risk of skin puncture. Work practice controls govern the handling of sharps such that the risk of skin puncture is minimized. Sharps are stored in rigid containers designed so that materials cannot be removed once they are placed inside the container. Containers must be clearly labeled, indicating the contents. When containers are two-thirds full, they must be sealed and rendered noninfectious prior to transport and final disposal.

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Regulated medical waste is either incinerated or disposed of in landfills. However, infectious or potentially infectious waste generated in a containment facility is first inactivated and rendered noninfectious by either chemical or physical means. Prior to transport to incinerators or landfills, RMW must be packaged in rigid, leak-proof containers which are resistant to moisture and strong enough to prevent tearing or bursting. Liquid RMW must be placed in tightly sealed, break-resistant containers. All RMW must be labeled and records of its movement from generation site to disposal site maintained.

2.5.4.5 Transport and Disposal of JVAP Vaccines

Vaccines developed under the JVAP are handled, as any vaccine would be, according to Federal, state and local regulations. Under Federal regulations and the regulations of the International Air Transport Association (IATA), vaccines are not classified as biohazardous waste and do not require special handling. Outdated or rejected vaccines are destroyed by the holding agency or state agency. The presence of two employees of the agency as witnesses to the destruction is required as mandated by 41 CFR § 101-45.903. The manner of disposal of outdated or excess vaccine product is dependent upon the nature of the vaccine that is being disposed. All vaccines are autoclaved, or incinerated in a permitted incinerator, and then buried in a sanitary landfill by a licensed medical waste contractor. All “live” vaccines are autoclaved prior to burial. All material is disposed of in a manner that prevents its identification as medical waste.

2.5.5 Use, Handling, and Disposal of Radioisotopes

In the course of implementing the proposed action, radioisotopes might be used to label proteins or nucleic acids for DNA sequencing. The use, handling, and disposal of radioactive materials fall under the jurisdiction of the U.S. Nuclear Regulatory Commission (NRC). The NRC rules direct that radioactive material must be used by or under the supervision of experienced scientists (specifically named on the license) whose expertise in the use, handling, and disposal of radioisotopes has been approved by the NRC. Institutions designate a Radiation Safety Officer (RSO) who then assumes responsibility for supervising all work involving radioactive materials. The RSO ensures that work complies with applicable NRC regulations and the terms of the NRC license. The RSO reviews protocols requiring the use of radioactive materials and provides expert advice and assistance in the resolution of problems. The RSO develops and implements use, storage and handling procedures, personnel and laboratory monitoring procedures, maintains accident and incident reports, approves purchase requests, and maintains a record of these activities.

Records describing the delivery, use, and disposal must be maintained separately for each isotope in order to comply with the requirements of 10 CFR § 20.401(b). Radioactive material waste disposal procedures vary with isotope, form (solid, liquid), and the type of waste with which it may be mixed (biological, solvent, aqueous). Procedures for the disposal of radioactive wastes must be detailed in written protocols which incorporate all relevant state, local, and Federal

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regulations and guidelines. No radioactive waste may be disposed of without the consent and knowledge of the RSO and all radioactive waste material must be labeled with the isotope name, its activity, date of assay, and date of disposal.

Radioactive material including mixed waste contaminated or potentially contaminated with infectious material is first sterilized by chemical treatment prior to disposal as radioactive waste. Organic liquid waste (e.g., scintillation vials containing less than 0.05 microcuries hydrogen-3 or carbon-14 per gram of scintillation medium) is disposed of as chemical waste.

Depending upon NRC license terms, a facility may be authorized to hold radioactive material with a physical half-life of less than 65 days (e.g., phosphorus-32 and sulfur-35) for decay-in-storage before disposal in ordinary trash, providing that the radioactive waste material is held for a minimum of ten half-lives. A radiologic survey must first indicate that the radioactivity has diminished to the point where it is indistinguishable from the level of background radiation before such waste may be disposed of as routine solid waste. Prior to disposal, all radiation labels must be removed or obliterated.

Under the requirements of 10 CFR § 20.303, some waste isotopes are permitted to be disposed of via the sanitary sewer. These wastes include liquid radioactive waste which is readily soluble or dispersible in water and diluted in accordance with 10 CFR Part 20, Appendix B, Table II, column 2. Records of the quantities and isotopes of materials disposed of in the sanitary sewer must be maintained by authorized users.

Individuals working with radioactive material must be monitored for radiation exposure as indicated by the characteristics of the radioisotopes with which they work and in accordance with 10 CFR Part 20, *Standards for Protection Against Radiation*.

Contractors must provide the DA with a list of the radioactive substances they will use in the conduct of work as well as information about administrative procedures and internal regulations for complying with Federal, state, and local regulations pertaining to radioactive wastes. Regulatory compliance with regards to ionizing and non-ionizing radiation must be demonstrated.

2.5.6 Use, Handling, and Disposal of Hazardous Chemicals

There are numerous laws and regulations governing the use, handling, and disposal of hazardous chemicals. All activities conducted in implementing the proposed actions must comply with Federal hazardous waste regulations (40 CFR Parts 260-266), applicable state and local hazardous waste laws, DOT hazardous materials regulations (49 CFR Part 171), and Federal regulations governing occupational exposure to hazardous materials (29 CFR Part 1910), Resource Conservation and Recovery Act (RCRA) permitting and state authorization regulations (40 CFR Parts 270 and 271), regulations governing underground storage tanks (40 CFR Part 280), used oil (40 CFR Part 279), and universal waste (40 CFR 273). Contractors must submit a

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hazardous chemical list as required by the 1986 Superfund Amendments and Reauthorization Act (SARA) Title III, Emergency Planning and Community Right-to Know.

AR 385-10 requires that operations involving the use, handling, storage, and disposal of hazardous chemicals be conducted in accordance with the policies and procedures of a Chemical Hygiene Plan (CHP), developed for the operation, as required by 29 CFR Part 1910. The CHP must be a comprehensive plan describing responsibilities, policies, and procedures for all aspects of the handling of hazardous chemicals in the laboratory.

The OSHA standards which protect workers from exposure to hazardous and potentially hazardous chemicals in the workplace require that employees receive information and training concerning all of the chemicals they use and to which they may become exposed (29 CFR § 1910.1045, Hazard Communication). Under these rules, laboratory supervisors or other designated individuals must ensure that all personnel have received adequate training. The chemical health and safety information that must be made available to personnel includes the contents of the OSHA Laboratory Standard (and Appendices), the location and availability of the CHP, Permissible Exposure Limits (PELs) for OSHA-regulated substances, and explanation of and information regarding the location of Material Safety Data Sheets (MSDSs), and the physical and health hazards of the chemical which the personnel will be using. The MSDSs for chemicals used in each site of operation must be located in an easily identifiable location within each laboratory.

Operations performed under the JVAP program must comply with the OSHA Hazard Communication Standard which mandates access to information and training regarding the handling, use, and storage of designated hazardous chemicals (29 CFR § 1910.1200). To comply with this standard, each facility or site safety office or designated individual must maintain a list of all hazardous chemicals. Each individual laboratory must maintain a list of the chemicals used within the laboratory, and persons in the laboratory are responsible for being informed about the hazards associated with exposure to and use of the chemicals with which they work. Material Safety Data Sheets must be available for all chemicals on the inventory list. With the exception of chemicals under development in research laboratories, an MSDS must be available in each laboratory for each hazardous chemical present. The procedures which a facility uses for implementing this regulation (and 29 CFR § 1910.1450) must be detailed prior to contract award.

Joint Vaccine Acquisition Program provisions require that the government be notified if a contractor is or has been informed by the EPA that it is listed, or under consideration to be listed, on the EPA List of Violating Facilities.

2.5.7 Worker Health and Safety

2.5.7.1 Occupational Health

Issues concerning worker health and safety at private sector facilities are regulated in part by OSHA rules. Federal facilities are required to develop and execute their own regulations implementing OSHA standards. This includes implementing 29 CFR § 1910.1030, Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standard. The OSHA Bloodborne Pathogen Standard was developed to reduce occupational exposure to hepatitis B virus, human immunodeficiency virus, and other pathogenic agents potentially transmitted by blood and blood products. All personnel employed or contracted by the DA are required to comply with this standard. Methods of compliance entail engineering and work practice controls and the use of personal protective equipment. Engineering controls include the use of biological safety cabinets which physically isolate personnel from biological hazards. Work practice controls include performing tasks using techniques that reduce the likelihood of exposure to biological hazards. The possibility of a biological hazard coming into contact with a worker's clothes, skin, eyes, or mouth is limited by use of personal protective equipment including face shields, gloves, clothing, masks, engineering controls (e.g., HEPA filtration) and laboratory practices.

Potential JVAP contractors must submit descriptions of building/laboratory ventilation features and their conformance to current recommended practices [American Conference of Governmental Industrial Hygienists (ACGIH) Industrial Ventilation]. In addition, they must provide descriptions of the waste air streams emanating from biological safety cabinets and chemical fume hoods, and their adherence to standards. Contractors must provide documentation about the availability of personal protective equipment and the procedures in place for maintenance and repair of same. Respiratory protection programs must be operated in accordance with 29 CFR 1910.134 and details must be submitted to the contracting agency.

2.5.7.2 Medical Monitoring of JVAP Workers

The medical monitoring of personnel engaged in work with biological defense etiologic agents is detailed in AR 385-69. AR 385-69 requires that new employees be given an initial medical examination which includes the collection of baseline blood samples. Thereafter, employees receive periodic physical examinations and a physical examination at the termination of their employment or their work with biological defense agents. Employees are required to undergo immunization against biological agents with which they work and are monitored for serologic evidence of exposure and/or infection at least annually.

Contractors must submit information about specific treatment resources for hazards unique to the proposed activities, the availability of local emergency medical care, the personnel designated as points of contact for advanced treatment resources and consultation, and details of their routine medical monitoring/occupational health program including the frequency of monitoring.

2.5.7.3 Medical Monitoring of Vaccine Recipients

Once licensed and produced for distribution, neither the decision to administer nor the administration of a particular JVAP vaccine or toxoid to soldiers is within the scope of the JVAP. Such decisions and actions will be managed by the Secretary of Defense on advice from the Assistant Secretary of Defense for Health Affairs as implemented through the Secretaries of the military departments and the Joint Chiefs. Biological defense vaccines will be administered to military personnel through DoD's medical delivery systems. Once a licensed vaccine has been administered there are a several ways by which biological defense vaccine recipients will be monitored. Adverse vaccine events must be reported through the Vaccine Adverse Event Reporting System (VAERS). The VAERS is a civilian surveillance system established in 1990 and managed by the FDA and the CDC. The primary purpose of the VAERS is to identify rare and previously unrecognized reactions to vaccines (especially newly marketed vaccines) and to monitor the safety of particular lots of vaccines. The data included in this reporting system are date of birth, description of the adverse event, date of vaccination, date of onset of adverse event, and vaccines administered.

Anyone may submit a report to the VAERS although most reports are received from vaccine manufacturers, health care providers, and state health coordinators. Historically, most of the reports received by the VAERS are for reactions seen in young children. Food and Drug Administration physicians are responsible for investigating all deaths reported and for reviewing selected serious cases. Serious events are also followed by the FDA for recovery status.

MedWatch is another system for reporting serious adverse events resulting from vaccines. It was established in June 1993 and is also managed by the FDA. This system differs from the VAERS in that most of its reports are through health care practitioners and it gathers information not only on vaccines but also drugs and medical devices. Data included in this system are age, sex, and weight of the patient; adverse event; date and description of the adverse event; other relevant patient history and test results; a description of the suspect medication or device; and reporter information.

In addition to these systems for monitoring reactions to FDA-regulated products, the DoD and DA have surveillance activities underway or in development for surveying adverse health events and their potential causes. The USAMMA collects information about product quality control; the Center for Health Promotion and Preventive Medicine collects information about illnesses within the military population; and the USAMRMC collects information on investigational products. Additional military surveillance systems include the Army Medical Surveillance Activity, the Defense Medical Epidemiology Database, and the Uniformed Services Prescription Database Project (Institute of Medicine, 1996). The purpose of these activities is to enhance understanding about the health and well-being of service personnel by gathering and integrating medical information on individuals as well as information concerning possible exposures. Through the use of linkable databases, researchers will have tools to correlate (relate or compare)

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health impacts seen within select populations (e.g., vaccine recipients) to specific treatments (e.g., vaccines) and/or exposures to hazardous substances or infectious agents.

2.6 CARE AND USE OF ANIMALS

The use of laboratory animals will be required in the activities supporting and resulting in the production of biological defense vaccines. The number of each type of animal required in the implementation of the proposed action cannot be determined at this time. The care and use of laboratory animals must comply with standards and guidelines specified in AR 70-18 (*The Use of Animals in DoD and DoD-Sponsored Programs*) which incorporates Federal and DoD regulations and policies including requirements of the Animal Welfare Act (9 CFR Part 14). The Animal Welfare Act sets standards for humane animal care, handling, treatment, transportation, requires licensing of animal dealers, and has provisions for the registration of animal facilities. Compliance with 21 USC 154 which regulates the use of harmful or dangerous viruses, serums, toxins, and other agents in animals in facilities producing or testing biological products is also required. Animal handling practices and the quality of care must comply with the *Guide for the Care and Use of Laboratory Animals*, DHHS Publication 86-23 (National Research Council, 1985). Accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care International [formerly known as the American Association for the Accreditation of Laboratory Animal Care, (AAALAC)] is sought by all DA facilities using animals. The AAALAC accredits active animal care and use programs that maintain, use, import, or produce animals for scientific research, teaching or testing. The AAALAC defines active animal care and use programs as including animals; facilities; equipment; professional, technical, and administrative support; and policies and programs for institutional responsibilities, animal husbandry, and veterinary care. The DA and DA contracting officers may suspend all work at a JVAP facility if noncompliance is determined.

Safety/containment practices used during vaccine animal testing must meet or exceed characteristics of ABL recommended in the CDC/NIH Guidelines. Animal biosafety levels include animal handling practices, protocols, equipment, and facilities appropriate for work with infected animals, and correspond to the level of risk associated with the etiologic agent involved. These practices include decontamination of all surfaces after spills, prohibition of smoking, eating, and drinking in animal rooms, washing of personnel hands after handling cultures, and inward opening doors to rooms housing infected animals. In the event that an individual is bitten or scratched by an animal, or is stuck by a needle which has been used on an animal, he/she is required to report this to the supervisor or safety officer and must report to the emergency room for appropriate medical care. In addition to these procedures, cages are autoclaved prior to cleaning activities and animal disposal, and personnel must wear protective boots, surgical masks, gloves, and solid-front/wrap-around type gowns when work with infected animals is in progress. All infected animal wastes are autoclaved and incinerated. Leak-proof containers are used when transporting animal carcasses.

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Work with laboratory animals that is conducted outside of the continental U.S. must comply with all laws, customs, and practices of the country in which it is conducted. According to the JVAP RFP, “In those instances where the local laws and regulations are in conflict with the laws and regulations of the United States and the Department of Agriculture, the more humane and stringent will be followed.”

2.7 USE OF HUMAN SUBJECTS

Clinical trials of investigational vaccines will involve the use of a small number of human subjects (see Sections 2.4.3 and 2.4.4). Studies involving the use of human subjects receive oversight by several authorities and must comply with 10 USC § 980 (Requirement for Obtaining Informed Consent), 32 CFR Part 219 (Federal Policy for the Protection of Human Subjects, DoD), AR 70-25 (Use of Volunteers as Subject of Research), FDA regulations (21 CFR Part 50, Protection of Human Subjects and 21 CFR Part 56, Institutional Review Boards), DHHS regulations (45 CFR Part 46, Protection of Human Subjects) and all other applicable Federal, state, DoD, and DA regulations and guidelines. In addition to compliance with U.S. regulations for protection of human subjects, review and approval for clinical protocols must be obtained by host nation authorities when a protocol is conducted in a country other than the U.S.

The FDA’s regulation concerning the administration of INDs to humans requires that prior to commencing study in humans, the investigator must obtain approval from an institutional review board as well as written informed consent from research subjects. Although not involved in clinical trials *per se*, individuals such as laboratory and production workers must also give their written informed consent prior to receiving IND vaccines or toxoids as part of their occupational health programs. Records of adverse effects resulting from use of INDs must be maintained and reported to the FDA.

Exceptions from the general requirements for informed consent may be allowed in cases where informed consent is not considered feasible or is contrary to the patient’s interests (21 CFR § 50.23). The FDA may consider requests from the Assistant Secretary of Defense (Health Affairs) for exceptions to the general requirement for informed consent with the use of an IND. Such requests are limited, however, to “a specific military operation involving combat or the immediate threat of combat.” Requests for such determinations are submitted to the Commissioner of the FDA and must include written justifications and rationale as well as statements from an institutional review board. In making a determination, the FDA is required to consider the extent and strength of evidence of the safety and effectiveness of the IND for its intended use; the context in which the IND will be administered; the nature of the disease for which the IND is intended; and the nature of the information that will be provided to the IND recipients regarding the benefits and risks of taking or not taking the IND.

3.0 ALTERNATIVES

3.1 IDENTIFICATION OF ALTERNATIVES

An EA must identify and explain the “range of alternatives.” The range of alternatives includes all reasonable alternatives, which must be explored and objectively evaluated, as well as those other alternatives, which are eliminated from detailed study with a brief discussion of the reasons for their elimination (40 CFR 1502.14(a)).

The proposed action and subject of this PEA is the conduct of current and currently planned activities associated with implementing the JVAP. During the preparation of this PEA, three reasonable alternatives in addition to the proposed action were identified. The reasonable alternatives identified included the cessation of all JVAP activities now and in the future (Alternative II - the no-action alternative); the conduct of JVAP activities in a consolidated government facility (Alternative III), and the conduct of JVAP activities at a consolidated contractor facility (Alternative IV).

3.2 REASONABLE ALTERNATIVES

The four alternatives comprising the range of reasonable alternatives examined in this PEA are discussed below.

3.2.1 Alternative I - Continue Current and Currently Planned JVAP Operations

Operation of the JVAP in its planned scope is considered the preferred alternative because it is the option which best meets the needs of the national defense. The DoD Mission Needs Statement for Biological Defense articulates the importance of medical biological defense products to military readiness. The DoD has determined that the most cost effective and expedient manner in which to meet these needs is through implementing a prime systems contract (see Sections 2.2 and 2.3). In addition, establishing the JVAP will create an integrated approach to accomplishing these goals (see Sections 1.2, 2.2, and 2.3). The current and currently planned activities of the JVAP will provide mechanisms for developing and producing vaccines for the military requirements, as the Deputy Secretary of Defense has directed, through a prime systems contract with oversight by the DAB. The JVAP prime systems contractor will coordinate and incorporate the work of subcontractors and other associated organizations to optimize all aspects of product development, licensure, production, testing, distribution, and compliance with regulatory requirements.

3.2.2 Alternative II - Cease Current and Currently Planned JVAP Operations (No Action)

This alternative involves cessation of JVAP operations (no action). This alternative is not preferred because the cessation of JVAP would impair national defense posture by impeding the

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development and production of biological defense vaccines for which a need has been determined (see Section 1.2).

3.2.3 Alternative III - Conduct Current and Currently Planned JVAP Operations in a Consolidated Government Facility

This alternative is similar to Alternative I except all JVAP activities would be conducted at a government-owned and -operated facility. This alternative is not the preferred alternative because it would require the renovation of an existing facility or the construction of a new facility, which will cause some adverse impacts. Concentrating activities in one geographical location may potentially overburden existing waste stream management facilities (e.g., wastewater treatment plant, incinerators) and local utilities (e.g., water and power).

3.2.4 Alternative IV - Conduct Current and Currently Planned JVAP Operations in a Consolidated Contractor Facility

This alternative is similar to Alternative III except that contractor personnel would staff the program. The program would be conducted in unspecified contractor-owned facilities. The environmental impacts of Alternative IV may include the potential environmental impacts associated with concentrating JVAP activities in one geographical location. In the event that existing facilities were unavailable or inadequate, potential environmental impacts associated with renovation of an existing facility or the construction of a new facility may also result.

3.3 REJECTED ALTERNATIVES

After careful consideration and study, two alternatives were rejected from further consideration as unreasonable under the circumstances. The reasons for their elimination are discussed briefly below. The rejected alternatives included the purchase of biological defense vaccines from an existing source, and the elimination of one or more vaccines from the list of those planned for development and production. In accordance with 40 CFR 1502.14, these alternatives will not be further explored or evaluated within this PEA.

3.3.1 Rejected Alternative - Purchase Biological Defense Vaccines from an Existing Source

This alternative entails the government implementing its biological defense vaccine policy by purchasing vaccines from existing sources. This alternative is rejected from further consideration as unreasonable because the government has determined that such sources do not currently exist and are unlikely to become available in the foreseeable future (see Section 1.2) (JPO BD, 1995).

3.3.2 Rejected Alternative - Eliminate One or More Vaccines from Consideration for Development and/or Production

This alternative entails implementing the proposed action in an abbreviated form. This alternative has been rejected from further consideration as unreasonable because it does not meet the needs identified by the Deputy Secretary of Defense and the Joint Chiefs of Staff with regards to identified biological warfare threats (see Section 1.2).

4.0 AFFECTED ENVIRONMENT AND ENVIRONMENTAL AND SOCIOECONOMIC CONSEQUENCES OF THE PROPOSED ACTION

4.1 INTRODUCTION

In this section, the potential environmental consequences of each of the JVAP phases described in Section 2 is discussed. The purpose of this section is to identify and analyze potential cause and effect relationships which may exist between the JVAP actions and their impacts, if any. Such an analysis entails examining the impacts associated with the conduct of current and currently planned JVAP activities that may not necessarily occur, but which are reasonably foreseeable. This analysis determines if implementing the JVAP has the potential for significant environmental impacts. It also serves to inform decision makers and the public in making reasonable choices among the alternatives.

The term “consequence” refers to the results of an event or events without consideration of probability. Where possible and appropriate, potential events are characterized both in terms of their potential consequence and the probability that they will occur. Consequences of JVAP operations on the public, on workers, and on vaccine recipients are considered. Direct, indirect and cumulative effects also are considered.

4.2 ASSESSMENT APPROACH

An accurate assessment of the potential environmental consequences of the JVAP can be made by using previously conducted environmental analyses of activities which are similar or identical in scope to those that will be conducted in the JVAP. However, the scope of this PEA is inherently limited by both the extended time duration of the JVAP and the fact that some sites of JVAP execution are unknown at this time. This PEA therefore incorporates analyses from previous NEPA analyses which assessed actions with similar activities and potential impacts to the proposed action (see Section 2.0). This approach entails referencing specific relevant analyses, discussions, and conclusions of those documents without providing detailed discussions in this PEA. The analyses referenced from previous NEPA documents will be summarized and updated (BDRP FPEIS, 1989; USAMRIID EA, 1991; MDPH EA, 1993; TSI-GSD EA, 1992; WRAIR EA, 1993; Battelle EA, 1993; USAMRICD EA, 1992). The applicability of these NEPA documents to particular phases of the JVAP is provided in Table 4-1. Additional site-specific NEPA analyses for the JVAP sites may be required in the future (see Section 4.3).

The analyses performed in the BDRP FPEIS included examination of general laboratory activities; laboratory work involving the use and handling of biological defense etiologic agents (microorganisms and toxins); decontamination of materials, equipment, and/or laboratories; and

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TABLE 4-1. SELECTED NEPA ANALYSES RELEVANT TO THE JVAP

	Joint Vaccine Acquisition Program Scope			
		MSI	MSII	MSIII
NEPA Documentation	Contract	Phase I Program Definition & Risk Reduction	Phase II Engineering & Manufacturing Development	Phase III Production & Fielding
Biological Defense Research Program Final Programmatic EIS, 1989				
U.S. Army Medical Research Institute of Infectious Diseases EA, 1991				
Anthrax Vaccine Production and Testing at the Michigan Department of Public Health EA, 1993				
The Salk Institute-Government Services Division EA, 1992				
The Walter Reed Army Institute of Research EA, 1993				
EA for Battelle’s BL-3 Lab, 1993				
The U.S. Army Medical Research Institute of Chemical Defense EA, 1992				

the disposal of biological materials. These analyses also considered the transport of biohazardous organisms into and out of facilities; waste stream management; facility operation and maintenance; animal care and use; and the testing of products or product prototypes in human volunteers.

The environmental impacts of the production of FDA-licensed biological defense vaccines have been analyzed in the MDPH EA (anthrax vaccine) and in the TSI-GSD EA (vaccinia, WEE, EEE, VEE, Q-fever, tularemia, and anthrax). The MDPH is now known as the Michigan Biologic Products Institute (MBPI). Among its other activities, the MBPI Vaccines Section produces and tests anthrax vaccine for the DA. The TSI-GSD is a biological products scale-up manufacturing facility under contract to the U.S. Government, which develops, produces, and tests

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investigational vaccines for clinical trials. In addition, both MBPI and the TSI-GSD receive, store, inventory, and ship vaccines as directed. These two facilities conduct activities which are identical to activities which will be performed under the JVAP.

In the following sections (Section 4.4.1 through Section 4.4.20) each environmental component and the major regulations pertaining to its management and protection are described. The historical experience from similar activities is then used to predict potential environmental consequences from JVAP activities and the alternatives. In Section 4.5 the potential environmental impacts of implementing the proposed action and the alternatives are summarized and compared.

4.3 FUTURE ENVIRONMENTAL CONSIDERATIONS

The timeframe required for implementing the full extent of the proposed action is lengthy (greater than 10 years) and site-specific environmental analyses cannot be made at this time because some sites of program performance have not been determined. The impacts of future actions will be examined in the context of NEPA and AR 200-2 to determine whether environmental impacts are suitably addressed within this PEA or are sufficiently different to require separate NEPA documentation. It will be necessary for the DA to analyze subsequent actions relative to the JVAP which result in substantive changes in program conduct and/or site-specific assessments in the most appropriate NEPA format. For example, each geographical location where JVAP actions will be performed may require the U.S. Government to perform site-specific evaluation of the attributes of the environmental baseline described below. In accordance with both NEPA and AR 200-2, any subsequent NEPA analyses may be tiered to this PEA. This PEA, therefore defers detailed analyses of issues related to the future conduct of the program at a specific geographical location, or issues related to specific products. At a minimum, environmental analyses will be completed prior to award of future contracts and prior to execution of contract options shown in Table 2-1.

As discussed in Sections 1.1, 2.4.2.2, and 2.4.3.3, the FDA simultaneously licenses both products and the establishments in which products are made. Applications for JVAP product licenses must include a product-specific assessment of potential environmental impacts. The FDA requires that product specific assessments analyze and list the substances expected to be emitted from the establishment into the environment; the fate of emitted substances in air, water, and terrestrial ecosystems; the environmental effects of released substances, including effects on humans; energy and resource use; and mitigation measures (21 CFR § 25.31 (a)).

4.4 ENVIRONMENTAL CONSEQUENCES OF JVAP ACTIVITIES

This section of the PEA describes and assesses reasonably foreseeable impacts of the proposed action (see Section 2.0) and the alternatives. For each environmental attribute described below, the major applicable federal regulations are described and discussed. A summary and comparison of the likely environmental consequences of the proposed action and the alternatives are provided

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in Section 4.5. Although some sites of program execution have not been selected, the regulatory framework in which all JVAP activities must be conducted can be described based on the past conduct of similar activities.

4.4.1 Plant and Animal Ecology

Potential impacts to plant and animal resources could occur from JVAP activities involving inadequate waste stream management or the use of animals in research and production activities. The NEPA and the Endangered Species Act of 1973 (PL 93-205) are the primary mandates relative to protection, enhancement, and management of natural resources. The Endangered Species Act prohibits Federal agencies from placing threatened or endangered species at risk, or adversely modifying their critical habitats. These regulations also require maximum cooperation with state and local officials on natural resource issues.

In no instance have activities similar to those which will be conducted under the JVAP been demonstrated to impact the plant and animal ecology of the site (BDRP FPEIS, 1989; USAMRIID EA, 1991; MDPH EA, 1993; TSI-GSD EA, 1992; WRAIR EA, 1993; Battelle EA, 1993; USAMRICD EA, 1992; USAMRMC, 1997). It is unlikely that the conduct of the JVAP will impact the plant and animal ecology of the sites of JVAP execution because potential impacts will be mitigated by adherence to regulations regarding protection of wildlife and waste disposal. The environmental consequences associated with Alternative II (No Action) would be elimination of these negligible impacts to surface water. The potential impacts resulting from implementation of Alternative III (Consolidated Government Facility) or Alternative IV (Consolidated Contractor Facility) also would be negligible to the plant and animal ecology of the region adjacent to the JVAP site. Wildlife and/or endangered species will not be used in the conduct of JVAP activities.

4.4.2 Land Use

Joint Vaccine Acquisition Program activities may potentially impact land use patterns if those activities are not in character with the designated land use. Existing land use patterns in the vicinity of JVAP sites may include commercial and retail establishments, parking lots, residential areas, industry, and recreational and agricultural areas. Land use at the JVAP sites will likely be governed by local zoning ordinances, permits and existing land use patterns.

In all previous cases, the conduct of similar or identical activities which will be performed under the JVAP have been in accordance with existing land use patterns (BDRP FPEIS, 1989; USAMRIID EA, 1991; MDPH EA, 1993; TSI-GSD EA, 1992; WRAIR EA, 1993; Battelle EA, 1993; USAMRICD EA, 1992; USAMRMC, 1997). It is not anticipated that land use will be negatively impacted by current or currently planned activities of the JVAP. The conduct of the JVAP is likely to conform to existing land use patterns since activities will be conducted in existing facilities and new construction will not be required. The environmental consequences associated with Alternative II (No Action) would be elimination of the negligible to minor

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impacts to land use. Implementation of Alternative III (Consolidated Government Facility) or Alternative IV (Consolidated Contractor Facility) has more potential to disrupt land use patterns because of extensive renovation and/or new construction. Potential land use impacts are considered in the process of selecting contracting facilities for use in production.

4.4.3 Environmental Justice

Executive Order 12898, *Federal Actions to Address Environmental Justice in Minority and Low Income Populations*, requires Federal agencies to address significant adverse impacts of their actions on minority or low income populations. The U.S. Census defines the poverty level as the income level, based on family size, age of householder, and the number of children under 18 years of age, that is considered too low to meet essential living requirements without regard to the local cost of living. A “poverty area” is defined by the Census Bureau as an area in which at least 20% of the population lives below the poverty level.

Activities which are similar to those which will be performed under the JVAP are conducted at seven representative sites in the U.S., including Washington, DC; Aberdeen Proving Ground, Harford County, MD; Fort Detrick, Frederick County, MD; Rockville, Montgomery County, MD; West Jefferson, Madison County, OH; Lansing, MI; and Swiftwater, Pocono Township, PA. The percentage of the population living below the poverty level is as follows: Washington, DC (16.9%); Harford County, MD (5.1%); Frederick County, MD (18.0%); Montgomery County, MD (4.2%); Madison County, OH (8.4%); Lansing, MI (19.4%); and Pocono Township, PA (8.8%). According to the above definition of a “poverty area,” Lansing, MI, Frederick County, MD, and Washington, DC approach this definition and therefore can be considered low income communities under Executive Order 12898.

Race refers to census respondents’ self-identification of racial background and includes persons who identify themselves in the broad categories of Caucasian, African American, Asian, and “other race.” Census data also include those individuals who identify themselves as of Hispanic origin which refers to ethnicity and may include Spanish-speaking persons of any race. The percentage of the minority population living in the area adjacent to each site is as follows: Washington, DC (70%); Aberdeen Proving Ground, MD (40%); Frederick County, MD (18%); Montgomery County, MD (23%); Madison County, OH (8%); Lansing, MI (26%); and Pocono Township, PA (3%).

Activities which are similar to those which will be performed under the JVAP have not resulted in significant adverse impacts to minority or low income populations in the past (USAMRMC, 1997). Because activities associated with the proposed action are not expected to result in significant adverse impacts to air quality, noise levels, visual resources, transportation systems, odors, utilities, energy supplies, waste generation, or historical and cultural resources, implementation of the proposed action or any of the alternatives is not anticipated to have any disproportionately high adverse human health or other environmental impacts on low income or

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minority populations. Potential future environmental justice issues will be assessed in site-specific NEPA analyses that will be tiered to this PEA.

4.4.4 Surface Water

Surface water resources include consideration of rivers, streams, wetlands, and floodplains. JVAP activities could potentially impact surface water resources if the wastewater from these activities is discharged without adequate treatment. Impacts to surface water resources could result if untreated wastewater from facilities conducting biomedical activities containing high concentrations of organic matter were allowed to enter a waterbody such as a stream or lake. Such untreated discharge would consume dissolved oxygen from the water possibly resulting in the death of aquatic life.

The handling and disposal of wastewater originating from research laboratories are regulated by DoD, Army, Federal, state, and local policies, guidelines, and regulations. Section 402 of the Clean Water Act (CWA) (40 CFR Part 230) mandates the National Pollutant Discharge Elimination System (NPDES) (40 CFR Part 122) and is implemented by the DA through AR 200-1. The EPA and/or state regulatory agencies regulate wastewater discharge. All point source discharges to navigable waters are required to possess a permit issued through the NPDES or State Pollutant Discharge Elimination System. The NPDES permit process includes application, issuance, and compliance monitoring. Wetlands are protected by Section 401 and Section 404 of the CWA which prevents unnecessary destruction of wetland communities from discharge of dredged or fill material (40 CFR Part 6).

Wastewater potentially containing etiologic agents will not be directly discharged to streams, rivers, lakes, or sanitary sewers without proper treatment. The treatment requirements for wastewater from biomedical facilities are described in CDC/NIH Guidelines (CDC/NIH, 1993) and AR 385-69. Etiologic wastes and materials with the potential for causing disease must be inactivated by physical (autoclave) or chemical means prior to removal from production suites or laboratory areas and prior to entering into the sanitary sewer system. Waste radioisotopes and materials contaminated with radioisotopes will be handled and disposed of according to NRC requirements.

Wastewater discharge compliance is a highly site-specific issue because the quality and quantity of pollutants which can be discharged are determined by the characteristics of the receiving water body and its use as designated by the state. Effluent limitations include restrictions on quantities, rates, and concentrations of chemical, physical, or biological components of the waste stream. The states are usually delegated authority to administer and monitor discharge permits within their jurisdictions. State regulations governing the qualitative and quantitative characteristics of the discharge may be more stringent than those of the EPA.

No significant impacts to surface water resources have resulted from research, development, test, and evaluation (RDT&E) activities and production of biological defense vaccines in the more than

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50 years of the conduct of these activities (BDRP FPEIS, 1989; USAMRIID EA, 1991; MDPH EA, 1993; TSI-GSD EA, 1992; WRAIR EA, 1993; Battelle EA, 1993; USAMRICD EA, 1992; USAMRMC, 1997). For example, after treatment the wastewater from TSI-GSD is discharged into a stream with the highest water quality designation used by the Commonwealth of Pennsylvania. Treated wastewater has been discharged from this site for nearly 30 years with no significant impacts to a highly sensitive trout fishery. Precise quantitative analysis of the contribution of wastewater generated by current or currently planned JVAP activities is not possible at this time. Specific quantities and the scale of operations will be determined and set forth when contractors obtain their permits. It is not anticipated, however, that current or currently planned JVAP activities will negatively impact surface waters. Wetlands would not be impacted since it is highly unlikely that wastewater would be discharged to a wetland. The environmental consequences associated with Alternative II (No Action) would be elimination of these minor impacts to surface water. The potential impacts resulting from implementation of Alternative III (Consolidated Government Facility) and Alternative IV (Consolidated Contractor Facility) also would be minor but may cause a burden on local wastewater treatment facilities. The BDRP FPEIS identified the potential impacts on surface water as an area of concern. However, potential impacts to surface water will be mitigated by adherence to appropriate regulations for treatment of wastewater and the use of prescribed methods of handling, use, and disposal of etiologic agents which effectively neutralize toxins and render microorganisms harmless prior to entry into the waste stream.

4.4.5 Groundwater

Treatment of wastewater from biomedical operations requires both on-site and off-site treatment. After the required treatment within the facility, wastewater from biomedical operations would be transported via underground pipes to a wastewater treatment facility. If these pipes leaked, substances in the wastewater could contaminate the groundwater. Energy for some biomedical facilities may be partially dependent on fuel oil stored in underground tanks on the property. Groundwater could be contaminated by fuel oil if one of these tanks developed a leak.

Groundwater protection is mandated by the RCRA (40 CFR Parts 261-270), the Comprehensive Environmental Response, Compensation, and Liability Act (40 CFR Parts 300-399), and the Safe Drinking Water Act (SDWA) (40 CFR Part 144) (adherence to RCRA provisions for management of hazardous wastes and solid wastes is discussed in, respectively, Section 2.5.4.4 and Section 2.5.6). Regulations regarding protection of groundwater resources are concerned primarily with possible contamination of groundwater by leachates from landfills, underground storage tanks, deep well injection of wastes, and hazardous wastes sites as well as the mismanagement of production operations which generate hazardous waste. The SDWA requires state agencies to identify and protect critical aquifer areas.

Previous NEPA analyses for similar and identical activities to those which will be conducted under the JVAP indicate no adverse significant impacts have resulted to groundwater resources (BDRP FPEIS, 1989; USAMRIID EA, 1991; MDPH EA, 1993; TSI-GSD EA, 1992; WRAIR

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EA, 1993; Battelle EA, 1993; USAMRICD EA, 1992; Laboratory Sewer System (LSS) EA, 1997; USAMRMC, 1997). For example, biomedical activities have been performed at Fort Detrick, MD for more than 50 years. The extensive underground sewage system (called the laboratory sewer system) on this installation has maintained its integrity for more than 50 years without impacting groundwater resources (LSS EA, 1997). Impacts to groundwater resources resulting from implementation of the proposed action or any of the alternatives would unlikely be negative because compliance with permits and the regulations cited above for protecting groundwater resources will mitigate impacts to groundwater at the sites of JVAP performance.

4.4.6 Geology

The geologic environment includes earth resources such as soil characteristics, topography, fossils, minerals, and bedrock composition. Joint Vaccine Acquisition Program activities could potentially impact geologic resources by causing erosion if the buildings do not conform to the topography and soil characteristics of the site and through soil erosion resulting from landfill disposal of some waste materials. Federal regulations governing geological impacts relate to protection of groundwater, surface water, and wetlands.

In no instance have activities similar or identical to those which will be conducted under the JVAP been shown to negatively impact the geology of the site (BDRP FPEIS, 1989; USAMRIID EA, 1991; MDPH EA, 1993; TSI-GSD EA, 1992; WRAIR EA, 1993; Battelle EA, 1993; USAMRICD EA, 1992; USAMRMC, 1997). Laboratory facilities have been situated in conformance with local topography and have not caused excessive erosion. In cases where renovation or new construction has occurred, erosion impacts have been characterized as negligible (MDPH, 1993; TSI-GSD, 1992). The contribution to erosion by landfill disposal of waste materials has been consistently characterized as negligible (BDRP FPEIS, 1989; USAMRIID EA, 1991; MDPH EA, 1993; TSI-GSD EA, 1992; WRAIR EA, 1993; Battelle EA, 1993; USAMRICD EA, 1992; USAMRMC, 1997). It is unlikely that the conduct of the JVAP will negatively impact geological resources because construction or extensive renovations are not planned. Implementation of the no action alternative would prevent these negligible impacts to geologic resources. The adverse impacts to geologic resources arising from implementation of Alternative III (Consolidated Government Facility) or Alternative IV (Consolidated Contractor Facility) are less certain because of the likelihood of renovation and/or construction of new facilities. Adverse impacts to local geologic resources would likely be greater if either Alternative III or Alternative IV is implemented because of renovation and/or construction impacts.

4.4.7 Historical and Cultural Resources

Historic and cultural resources include historic sites, architecturally important buildings, locations which have cultural significance to the local community, and unique geological locations. The National Historic Preservation Act of 1966, as amended (PL 89-665), mandates a national policy for protection and restoration of significant historic, architectural, archaeological, or cultural resources. The 1980 amendments to the act provide for historic preservation costs to be included

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in project planning and budgeting. The DA implements the National Historic Preservation Act through NEPA, AR 200-2, and AR 420-40, *Historic Preservation*. The State Historic Preservation Officer (SHPO) is primarily responsible for ensuring adherence to the National Historic Preservation Act. Joint Vaccine Acquisition Program activities could impact significant historical or cultural resources if conducted near significant sites in a manner which altered or lessened these resources, including disturbance of archaeological sites.

Negative impacts to historical and archaeological resources resulting from activities similar or identical to those which will be conducted under the JVAP have not been demonstrated (BDRP FPEIS, 1989; USAMRIID EA, 1991; MDPH EA, 1993; TSI-GSD EA, 1992; WRAIR EA, 1993; Battelle EA, 1993; USAMRICD EA, 1992; USAMRMC, 1997). Where significant historical and/or archaeological resources are present, adherence to applicable regulations has fully mitigated negative impacts (WRAIR EA, 1993). No impacts to significant historical or cultural resources would result from the no action alternative. Implementation of Alternative III (Consolidated Government Facility) or Alternative IV (Consolidated Contractor Facility) would have the greatest potential to adversely impact historical or cultural resources because renovation and/or construction would be required. The potential for JVAP activities to impact historical or cultural resources would be determined by the proximity to significant sites.

4.4.8 Agriculture

Agricultural resources include crops and livestock in the areas surrounding the JVAP sites. Section 1539 of the Farmland Protection Policy Act of 1981 (PL 97-98) regulates the protection of agricultural lands by minimizing unnecessary and irreversible conversion of farmland to nonagricultural uses by Federal programs and assuring compatibility with state, local and private programs governing farmland. The act pertains to prime, unique, and statewide or locally important farmland. Negative impacts to agricultural resources could occur if JVAP activities adjacent to agricultural areas lessened the agricultural characteristics of the land.

Agricultural resources have not been negatively impacted by similar or identical activities to those which will be performed under the JVAP (BDRP FPEIS, 1989; USAMRIID EA, 1991; MDPH EA, 1993; TSI-GSD EA, 1992; WRAIR EA, 1993; Battelle EA, 1993; USAMRICD EA, 1992; USAMRMC, 1997). In locations where JVAP activities have been conducted near agricultural resources, impacts to agricultural characteristics of the area have been negligible (MDPH EA, 1993; Battelle EA, 1993 EA). Because new construction is not required by the JVAP preferred alternative, agricultural resources are unlikely to be impacted. Adherence to the Farmland Protection Policy Act will fully mitigate any impacts to agricultural resources. Agricultural resources would not be impacted under the no action alternative. Implementation of Alternative III (Consolidated Government Facility) or Alternative IV (Consolidated Contractor Facility) has more potential to adversely impact agricultural resources because of the probability of renovation and/or construction.

4.4.9 Climate

There are no Federal regulations governing climate; however, the quality of air in the region may be influenced by the local climate. Potential impacts to air quality are discussed in Section 4.4.15.

4.4.10 Energy Resources

Depletable energy resources include oil, gas and coal as well as renewable energy resources such as solar, wind, and water. The Energy Policy Act of 1992 (EPA Act) and Executive Order 12902 (EO 12902), *Energy Efficiency and Water Conservation at Federal Facilities*, require Federal agencies to decrease energy use and implement conservation measures. The EPA Act authorizes the participation of Federal agencies in utility programs that increase energy efficiency and manage electricity demand. Executive Order 12902 of March 8, 1994 requires agencies to reduce energy consumption 30% (measured relative to 1985 energy use) by the year 2005. The goals of Federal agencies are to increase the use of solar and other renewable energy resources, minimize the use of petroleum-based fuel and develop programs designed to introduce cost-effective, energy efficient technologies.

In previous assessments of similar or identical activities to those which will be conducted under the JVAP, the amount of energy consumption related to these activities has been demonstrated to be negligible when compared to the total consumption of the area (BDRP FPEIS, 1989; USAMRIID EA, 1991; MDPH EA, 1993; TSI-GSD EA, 1992; WRAIR EA, 1993; Battelle EA, 1993; USAMRICD EA, 1992; USAMRMC, 1997). Precise quantification of the electrical energy consumption of current and currently planned JVAP activities and the adverse impacts on air quality due to the burning of fossil fuel is not possible at this time. Although the conduct of the JVAP will likely consume greater quantities of electricity per square foot than non-containment facilities, it is unlikely that these activities will adversely impact air quality. Implementation of Alternative II (No Action) would eliminate these negligible impacts to energy resources and air quality. The potential impacts resulting from implementation of Alternative III (Consolidated Government Facility) or Alternative IV (Consolidated Contractor Facility) also would be negligible to energy resources and air quality, although the impacts would be somewhat greater by concentrating activities in one location.

4.4.11 Noise

Negative impacts of noise on animals and humans include annoyance, permanent or temporary hearing loss, speech interference, sleep interference, health impacts, and harm to agricultural livestock and wildlife. The Noise Control Act of 1972 as amended (PL 92-574, USC 4901-4918) governs noise control for protection of public health. Generally, noise is regulated at the state and local level. Excessive noise levels from JVAP activities could impact the health of the workforce and the public, and alter the local plant and animal ecology.

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Noise impacts have not been identified as a significant concern in previous evaluations of similar or identical activities which will be conducted under the JVAP (BDRP FPEIS, 1989; USAMRIID EA, 1991; MDPH EA, 1993; TSI-GSD EA, 1992; WRAIR EA, 1993; Battelle EA, 1993; USAMRICD EA, 1992; USAMRMC, 1997). The activities which will be conducted under the JVAP are unlikely to produce high noise levels. Noise sources from JVAP activities could include transportation of employees and vendors to the site, and exhaust fans. The no action alternative would eliminate these negligible impacts of noise on the environment. Implementation of Alternative III (Consolidated Government Facility) or Alternative IV (Consolidated Contractor Facility) would temporarily increase the noise level at the site through renovation and/or construction activities. The impacts of noise on the environment associated with the operation of either consolidated facility would be somewhat greater than the noise levels associated with the proposed alternative. Noise levels resulting from activities at the JVAP sites will be evaluated on a site-by-site basis to determine the potential negative impacts on humans and animals.

4.4.12 Odors

Odors may be associated with certain JVAP activities such as incineration or heat treatment of wastes. The Clean Air Act (CAA) and state regulations govern odors associated with incineration and disposal activities.

Unpleasant odors resulting from activities similar or identical to those which will be conducted under the JVAP have been identified as an area of minor concern (BDRP FPEIS, 1989; USAMRIID EA, 1991; MDPH EA, 1993; TSI-GSD EA, 1992; WRAIR EA, 1993; Battelle EA, 1993; USAMRICD EA, 1992; USAMRMC, 1997). These odors, however, are transitory and rapidly diluted in the atmosphere. Adherence to applicable regulations governing disposal of wastes, particularly those related to incineration, will mitigate these minor impacts from JVAP activities to the local environment (see Section 4.4.15). Implementation of the no action alternative would eliminate these minor impacts. Odor impacts resulting from implementation of Alternative III (Consolidated Government Facility) or Alternative IV (Consolidated Contractor Facility) would likely be greater since odors would be generated and concentrated at one geographical location.

4.4.13 Socioeconomic Environment

Evaluation of potential JVAP impacts on the socioeconomic environment considers human relationships and interactions, with emphasis on economic issues. Socioeconomic components include demographics, aesthetics, employment, income, housing, and property values. The potentially affected population will include individuals who work at JVAP sites and their impacts on the local economy.

The conduct of activities similar or identical to those which will be performed under the JVAP have been shown to have a minor positive impact on local economies (BDRP FPEIS, 1989;

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USAMRIID EA, 1991; MDPH EA, 1993; TSI-GSD EA, 1992; WRAIR EA, 1993; Battelle EA, 1993; USAMRICD EA, 1992; USAMRMC, 1997). The economic impacts of the proposed action would likely be minor but positive to the local economies at the sites. The no action alternative eliminates these minor positive economic impacts. Implementation of Alternative III (Consolidated Government Facility) or Alternative IV (Consolidated Contractor Facility) is likely to cause a more significant positive impact to the local economy by concentrating all activities at one geographical location. Positive economic impacts would also result from renovation and/or construction activities. Each of the JVAP sites will be evaluated to determine if the proposed action will adversely affect minority or low income populations.

4.4.14 Transportation

Transportation resources include the capacity of existing roads, safety issues, and adequacy of parking and transportation systems.

Previous evaluation of the impacts of activities similar or identical to those which will be performed under the JVAP on local transportation resources indicated negligible impacts (BDRP FPEIS, 1989; USAMRIID EA, 1991; MDPH EA, 1993; TSI-GSD EA, 1992; WRAIR EA, 1993; Battelle EA, 1993; USAMRICD EA, 1992; USAMRMC, 1997). There is no reason to believe that the conduct of the JVAP will significantly impact transportation resources because JVAP activities will be conducted at existing sites and are unlikely to significantly add to existing traffic burdens. The no action alternative eliminates these minor transportation impacts. Implementation of Alternative III (Consolidated Government Facility) or Alternative IV (Consolidated Contractor Facility) has more potential to significantly impact local transportation networks since all activities would be consolidated at one geographical location. Potential impacts to the transportation component of the environment by the JVAP will be evaluated on a site-by-site basis in accordance with guidance provided in NEPA and AR 200-2.

Significant adverse impacts associated with the shipment of etiologic agents are unlikely because all shipments will be in accordance with Army regulations, contract terms, and other appropriate regulations. Shipment of etiologic agents will be in accordance 42 CFR Part 72 (Interstate Shipment of Etiologic Agents), 49 CFR Parts 172 and 173 (Department of Transportation Regulations), 9 CFR Part 122 (U.S. Department of Agriculture Restricted Animal Pathogens), International Air Transport Associated Regulations and the more restrictive biological defense safety regulations (32 CFR Parts 626, 627).

4.4.15 Air Quality

Evaluation of the air quality of the area surrounding JVAP sites includes examination of primary and secondary standards and emission standards for hazardous air pollutants (HAPs) as set forth in the CAA of 1990. Primary standards are designed to protect health, whereas secondary standards are intended to prevent environmental and property damage. According to the CAA, HAPs are chemicals that cause serious health and environmental hazards.

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The CAA of 1990 added new provisions for air toxics and tightened air quality standards. Under the CAA, the EPA adopted the National Ambient Air Quality Standards (NAAQS) to control a select group of widely occurring pollutants. The NAAQS pollutants are carbon monoxide (CO), nitrogen oxides (NO_x), sulfur dioxide (SO₂), volatile organic compounds (VOCs), lead, and particulate matter. The CAA also provides for more stringent standards for new medical waste incinerators. The application of these standards will result in significant reductions in incinerator emissions. The provisions of the CAA are only applicable to major sources (large).

Under the CAA, a geographic area in which levels of a criterion air pollutant meet the health-based primary standard (NAAQS) for the pollutant is called an attainment area. A non-attainment area is a geographic area in which the level of a criterion air pollutant is higher than the level allowed by the NAAQS. One single location may be in attainment for one pollutant and simultaneously have unacceptably high levels of another criteria air pollutant. Therefore, an area can be both in attainment and non-attainment at the same time.

Incinerators are classified as major sources of air pollution under the CAA. Incinerators located and operated at JVAP facilities will be subject to the provisions of the CAA. Additional restrictions will be applicable if the facility is located in an area that is non-attainment for any of the criteria air pollutants. The use of incinerators is regulated by Federal, state, and local laws which set standards and limits for emission volumes and composition, and in some states, the quality (including biological quality) of incinerator ash. Environmental control of biological air quality by HEPA filtration during routine operations of containment facilities is described in CDC/NIH Guidelines (CDC/NIH, 1993). JVAP activities could impact air quality and climate by increasing pollution through several pathways including energy consumption, commuting workforce, incineration activities, and air exhaust from biomedical laboratories.

Previous NEPA analyses indicate that adverse impacts to air quality resulting from biological defense RDT&E and vaccine production activities have been negligible (BDRP FPEIS, 1989; USAMRIID EA, 1991; MDPH EA, 1993; TSI-GSD EA, 1992; WRAIR EA, 1993; Battelle EA, 1993; USAMRICD EA, 1992; USAMRMC, 1997). Air emissions contributed by currently planned JVAP activities cannot be quantitatively assessed at this time. Specific quantities and the scale of operations will be set forth when contractors obtain permits. However, the impacts of energy consumption and the commuting workforce will likely be negligible components of the total air pollution of a region. Adherence to CAA provisions related to incinerators and local permits will ensure that other SO₂ and NO_x concentrations remain below limits determined to be adverse for local standards. Incineration activities may produce transiently offensive odors, but the CAA requires that new medical waste incinerators be much more efficient. As old incinerators are decommissioned, replacement with new medical waste incinerators will mitigate adverse impacts to air quality at those sites. The high efficiency of HEPA filtration in preventing the escape of etiologic agents from biomedical laboratories has been previously discussed in the CDC/NIH Guidelines (CDC/NIH, 1993) and the BDRP FPEIS. Therefore, the impacts of JVAP activities on local air quality will likely be negligible. These negligible adverse impacts to air

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quality would be eliminated under the no action alternative. Implementation of Alternative III (Consolidated Government Facility) or Alternative IV (Consolidated Contractor Facility) has more potential to significantly degrade local air quality because all air pollution would be concentrated in one geographical location, including air pollution resulting from energy consumption, transportation of the workforce and supplies, waste disposal activities of incinerators, and odors. The impacts of JVAP activities on air quality will be evaluated on a site-by-site basis.

4.4.16 Public Opinion

Public opinion toward a proposed action must be considered to the maximum extent practicable in accordance with NEPA and AR 200-2. Evaluation of public opinion includes an assessment of national and/or local perception of issues.

There is strong Congressional and public support for DoD's policy of providing our fighting men and women with the best protection possible against BW agents. Potential criticisms of JVAP activities may include the perceived potential for this research to be used for offensive purposes, the efficacy of biological defense vaccines, distrust of the military, the use of soldiers as research subjects, issues regarding informed consent of soldiers, and whether the military should be involved in vaccine production. Public opinion has been an issue in the conduct of biological warfare defense research and development activities and was extensively discussed in the BDRP FPEIS. Some public concerns relate to the existence of biological defense programs *per se*; others to the intent, need for, and benefits of such programs. Other concerns are specific to the impacts of actions, such as the use of animals in research, the use and handling of recombinant DNA technology, use of human subjects, the use of investigational products in military and civilian personnel, medical surveillance, and potential drug interactions. Issues such as these are not unique to the current or currently planned JVAP activities but are concerns associated with vaccine and/or biomedical research, development, and production activities in general.

The government and facilities supported by the government (e.g., MBPI, TSI-GSD) do not engage in work related to the production or use of offensive biological weapons as required by the *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction* (Biological Weapons Convention of 1972) to which the U.S. is a signatory.

The BDRP FPEIS examined the use of recombinant DNA technology and concluded that significant issues associated with its use were related to the existence of the program (BDRP) rather than to specific sites that were analyzed. The analysis performed in the BDRP FPEIS identified no actual significant adverse impacts resulting from the use of recombinant DNA technology. This conclusion has been validated by subsequent site-specific assessments (BDRP FPEIS, 1989; USAMRIID EA, 1991; MDPH EA, 1993; TSI-GSD EA, 1992; WRAIR EA, 1993; Battelle EA, 1993; USAMRICD EA, 1992; USAMRMC, 1997). JVAP activities involving the use of recombinant DNA molecules will represent a small fraction of research, development,

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pharmaceutical production and industrial application of genetically engineered microorganisms conducted nationally by universities, medical research establishments, and commercial entities.

Prior to the issue of each vaccine license for the production of vaccine, environmental analyses and evaluation will be submitted to the FDA by the contractor in the form of a REC, EA, or EIS. The FDA will consider the potential environmental impacts associated with approving the product for production and release. These analyses will describe the action involving the recombinant material; the production system employed (host microbe or cell line, genetic constructs); the work practice and engineering controls employed for containment; a description and validation report of the process used to inactivate materials prior to their disposal; mitigation measures planned should the production organism become contaminated; and discussion of the environmental fate of all materials with the potential for release into the environment (21 CFR Part 25).

4.4.17 Program Benefits

There are several programs throughout the DoD which are directed toward developing both medical (e.g., prevention, treatment) and non-medical (e.g., detection systems, protective gear) defenses against biological warfare agents. The DoD has determined that biological defense vaccines are needed for protecting service men and women against injury or death resulting from the hostile use of biological warfare agents. In addition, vaccines are used to protect personnel engaged in biological warfare defense research activities which put them at potential risk of exposure to these agents. DoD Directive 6205.3 (*DoD Immunization Program for Biological Warfare Defense*) emphasizes the importance of FDA licensure for resulting vaccines “to ensure that service members are afforded the same level of safety and protection as the civilian populace for similar medical products.” This has been reinforced by the Assistant Secretary of Defense for Health Affairs, the military departments, and the Joint Chiefs of Staff.

The JVAP creates an integrated approach to vaccine development, production, and fielding focused on obtaining FDA licensure for all products. The JVAP will include the use of a prime systems contractor who will, once selected, use information and materials from existing DoD programs to create and execute an integrated approach leading to FDA licensure and long-term production and stockpiling of each required vaccine. The licensing of biological products requires close integration between the manufacturing process and product testing and evaluation. Implementation of the JVAP will facilitate the integration required by the FDA. The prime systems contractor selected by the DA will be responsible to the FDA, and will function as the vaccine license holder, as well as the manufacturer for the DoD.

4.4.18 Human Health and Safety

Public and worker health and safety are paramount in the JVAP. The DA gives the highest priority to public and worker health and safety. The following presents safeguards for assuring public and worker health and safety.

4.4.18.1 Public Health and Safety

Risks to the public from current and currently planned JVAP activities are extremely small. Current and currently planned JVAP activities are not likely to pose a significant threat to public health and safety because of the use of carefully considered and applied safety/containment procedures and practices. In addition, the release of infectious agents from vaccine development and production activities to the environment is prevented by the decontamination of all potentially infectious liquid, air, and solid wastes prior to discharge.

The issue of public health related to vaccine development and production has been examined in the course of evaluating the operations of several biological defense medical research facilities (BDRP FPEIS, 1989; USAMRIID EA, 1991; MDPH EA, 1993; TSI-GSD EA, 1992; WRAIR EA, 1993; Battelle EA, 1993; USAMRICD EA, 1992; USAMRMC, 1997). There have been no instances of infection or disease in the surrounding communities resulting from the conduct of these activities and a very small number of laboratory acquired infections in workers (BDRP FPEIS, 1989; USAMRIID EA, 1991; MDPH EA, 1993; TSI-GSD EA, 1992; WRAIR EA, 1993; Battelle EA, 1993; USAMRICD EA, 1992; USAMRMC, 1997). This information is consistent with the experiences of a broad range of laboratories throughout the U.S. (CDC/NIH, 1993; USAMMDA, 1992; Sewell, 1995).

Local and/or state laws govern the security of property including trespass, physical damage, and theft. Typically these regulations permit the property owner to bar the general public from unauthorized entry into the facility and allow the erection of barriers. Local and/or state officials enforce laws protecting property. Security for physical grounds and laboratories at the sites of JVAP activities will be appropriate to the nature of the activities performed at the particular site. Security measures may include perimeter control, security personnel, locked doors, and controlled access to biologically hazardous materials. Security evaluations, including a risk/threat assessment, will be performed on a site-by-site basis for each site of JVAP activities.

Requirements regarding emergency planning and reporting on hazardous and toxic chemicals will be followed, including The Emergency Planning and Community Right-to-Know Act of 1986 (Title III, SARA). Contractors must provide the JPO BD with plans for communicating and coordinating with local emergency personnel including police and fire officials regarding the potentially hazardous materials used at the facility (see Section 2.5.3). Contractors are also required to have current MSDSs for the chemicals in use (see Section 2.5.6).

4.4.18.2 Worker Health and Safety

There are small risks to workers associated with the development and production of vaccines. Workers engaged in biological warfare defense activities risk exposure to the etiologic agents with which they work. However, the actual risk to the JVAP workforce of contracting disease is small and is further ameliorated by vaccination (by candidate vaccines) when available, redundant

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safety equipment, extensive safety procedures, and training (see Section 2.0). The lack of significant negative impacts associated with the conduct of similar work at facilities currently and historically engaged in the conduct of biological defense vaccine research, development, testing, and production of pilot lots is indicative that the actual risks to JVAP workers will be small.

Requirements regarding emergency planning and reporting on hazardous and toxic chemicals will be followed, including The Emergency Planning and Community Right-to-Know Act of 1986 (Title III, SARA). Contractors must provide the PM JVAP with plans for communicating and coordinating with local emergency personnel including police and fire officials regarding the potentially hazardous materials used at the facility (see Section 2.5.3). Contractors are also required to have current MSDSs for the chemicals in use (see Section 2.5.6).

Qualitative and quantitative evaluations of the risk to workers performing vaccine production activities have been previously performed. At the MBPI, there has been no case of laboratory-acquired anthrax resulting from occupational exposure since the 1950s (CDC/NIH, 1993; Kaufman, 1992). There has been only one incident involving two employees with symptomatic cases of Q-fever in more than 30 years of operation of TSI-GSD. There were no serious, lasting health consequences in these cases. There have been no cases of infection of family members of workers employed at MBPI or TSI-GSD. This is not to imply that there are not hazards associated with working with etiologic agents, but validates that consistent application of, and adherence to, recommended practices and procedures mitigate the probable and observed adverse impacts to worker health and safety. As indicated in Section 2.0, facilities engaged in the conduct of activities for the JVAP must comply with laws and regulations promulgated for worker safety by Federal, DoD, DA, and state agencies.

4.4.18.3 Health and Safety of Vaccine Recipients

Vaccine Recipients - It is anticipated that the recipients of the products developed and produced through the JVAP will be soldiers for whom the threat of possible exposure to biological warfare agents has been established, and workers with the potential for exposure to biological warfare agents through their roles in laboratories or production facilities. DoD policy directs that personnel assigned to high-threat areas, predesignated for possible crisis response, or those employees identified and scheduled for deployment on an imminent or ongoing contingency operation to a high-threat area should be immunized against biological warfare agents for which suitable vaccines are available. In addition, the CDC/NIH Guidelines (CDC/NIH, 1993) advise that when appropriate vaccines exist, workers should be vaccinated. AR 385-69 defines DA policy and guidance for the vaccination of workers engaged in work with biological defense agents.

Risks Associated with Vaccination - Vaccination with any product is not without risk. Biomedical researchers have and are continuing to improve many widely used vaccines (e.g., pertussis, measles, polio) to reduce the inherent risks associated with their use. As with “conventional” vaccines, there are potential risks associated with the administration of biological

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defense vaccines. Risks to vaccine recipients vary with each vaccine. Individuals also vary in their responses to vaccines. These risks include those reactions which are manifested with the initial administration of vaccine and those which are manifested at some later time.

DoD's experience with the use of licensed vaccines for biological defense is limited to anthrax vaccine. Recipients of the anthrax vaccine are estimated at 150,000 individuals involved in the Gulf War, 1,000 lab workers and individuals participating in DoD studies, and 400-500 doses/year for those individuals involved in non-DoD work. The safety record for this product is excellent. For example, adverse reaction reports (from 16,500 doses in several clinical trials) show that no reaction or mild reactions were reported in 86% to 97% of those individuals receiving the initial series, and 77% to 97% of those individuals receiving booster doses. During the 5-year period, severe local reactions were reported for 1% or less of the doses. All local reactions to anthrax vaccines were reversible. Only four instances of systemic reactions (e.g., chills, fever and aching) were reported for a 24-hour period, but resulted in no chronic or permanent health consequences. There have been no reports of adverse events related to anthrax vaccine received during or since the Gulf War.

Pentavalent botulinum toxoid (PBT) was also used during the Gulf War. Importantly, it has been in use for more than 30 years, mostly to protect at risk laboratory workers, under an IND sponsored by the CDC. Safety data on thousands of workers enrolled under this IND have been reported to the FDA. The safety record on this product is also excellent. Of the 15,369 PBT injections reported between 1966 and 1994, 90% produced either no reaction or a mild reaction (area of redness or inflammation of less than 30 mm in diameter), 8.2% reported moderate reaction (redness or inflammation between 30 mm and 210 mm) and about 0.5% reported severe reaction (redness or inflammation greater than 210 mm with limitation of arm motion or pain or tenderness in the armpit). Generalized systemic reactions (e.g., fatigue, chill, fever, headache, dizziness, muscle or joint stiffness) have been reported in about 5% of all injections administered. In no instance have chronic adverse effects been associated with injection of PBT.

Approximately 8,000 individuals received the PBT after deployment to the Persian Gulf during January and February 1991. Most of the 8,000 people received only two doses because the war ended quickly. A retrospective postcard survey was conducted 6 to 7 months later on 121 Marines for local and systemic reactions. They were chosen because they had not received the anthrax vaccine: recollection would be specific for PBT vaccination. No local reactions were reported by 73% of the PBT recipients; the remainder reported redness and/or swelling, or pain, either alone or in combination. No generalized or systemic reactions were reported by 97% of the recipients; the remainder of the recipients reported systemic reactions that did not limit their activity.

Anecdotally, FDA licensed toxoid vaccines against diphtheria and tetanus have been used to produce an immune response capable of neutralizing the biologic activity of these two toxins. The safety data for the PBT vaccines are consistent with what is expected for individuals who have received the similar licensed diphtheria and tetanus toxoid vaccines.

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FDA Regulations - There are several points in the life cycle of vaccine production where failures can occur, resulting in ineffective vaccines or vaccines which themselves cause adverse impact to human health. Factors which result in ineffective vaccines include low potency — the product is ineffective in achieving immunity in the recipient; product contamination from ineffective purification; product contamination from improper storage or handling; and failure of the initial biological process to produce the desired product.

Vaccines are regulated by FDA from the time of product design through large-scale clinical testing, product distribution, and use. Regulations consider the safety, purity, potency, and efficacy of vaccines. Vaccine safety is regulated through the reporting of the frequency of adverse events. Vaccine purity is assessed by monitoring for the presence of contaminants. Potency is a measure of the relative strength of a vaccine as compared to a standard developed from laboratory or animal testing. Efficacy is the percentage of an immunized population protected from subsequent challenge.

The FDA enforces regulations for maintaining data on the impacts of investigational products. Included among these data is information on each lot of product and the incidence of adverse effects. Investigational New Drugs must be administered under approved protocols and in accordance with rules governing informed consent. Records must be maintained on all individuals receiving IND products to enable long-term follow-up if indicated. Section 2.4 (Product and Establishment License Applications) discusses the conditions under which a license may be revoked. Included among these conditions are FDA's inability to gain access to a facility and failure of the manufacturer to conform to standards of safety, purity, or potency.

Policy exists for the protection of recipients of investigational vaccines. DoD Directive 6205.3 (*DoD Immunization Program for Biological Warfare Defense, November 26, 1993*) establishes policy, assigns responsibilities, and prescribes procedures for immunization of members of the DoD against validated biological warfare threats, and prioritization of research, development, testing, acquisition, and stockpiling of biological defense vaccines. This Directive establishes that when the only available vaccine for a biological threat is an IND product it is to be administered under 21 CFR Parts 50 and 312 and the established IND protocol and/or other applicable legal procedures.

Monitoring - There are several systems by which it is anticipated that adverse impacts of vaccines on laboratory workers, production workers, and soldiers will be monitored. These systems are required by DoD, DA, and FDA regulations. Following FDA product license approval, vaccine safety and efficacy will be monitored through reporting systems for adverse events (the VAERS—Vaccine Adverse Experience Reporting System and MedWatch—a voluntary reporting system). Phase 4 studies are used to monitor vaccine efficacy. The need for and parameters of Phase 4 trials will be agreed upon by the JVAP and FDA prior to product licensure. For additional information on FDA requirements which safeguard the recipients of

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vaccines see Section 2.7. For additional information about the medical monitoring of vaccine recipients, see Sections 2.4.5.3 and 2.5.7.3.

Interactive Effects of Vaccines and Other Agents - The potential for adverse interactions among vaccines and drugs, immunoglobulin products, other vaccine products as well as with other biologics has been studied. Appendix D has tables summarizing the findings from some of these studies. In general, individuals with a compromised (less effective) immune system from either genetic or disease processes (e.g., human immunodeficiency virus) are at greater than normal risk of adverse reactions. Selected drug effects (e.g., immunosuppression) may be altered by concurrent vaccine administration. Simultaneous and sequential exposures to combinations of vaccine products have resulted in reduced vaccine immunogenicity.

In considering the potential for adverse impacts in the target population, it must be remembered that service members must be in good health to serve and to be retained on active duty. Additionally, DoDD 6205.3 directs that vaccines be administered with enough lead time for recipients to develop immunity well before their potential exposure to threat agents. The health of the recipient population and the lead time for observing adverse health effects minimize the potential for adverse impacts. Additionally, should there be adverse impacts, effects would be restricted to the recipient with minimal or no potential for adverse impacts in the larger population.

The National Academy of Sciences, Institute of Medicine, Medical Follow-up Agency, Committee to Study the Interactions of Drugs, Biologics and Chemicals in the U.S. Military Forces recently prepared a report entitled *Interactions of Drugs, Biologics, and Chemicals in U.S. Military Forces* (Petersdorf *et al.*, 1996) which presented a preliminary evaluation of the potential for biologics and vaccines to interact with other substances which also may be administered to military personnel. The Committee did not find any basis for “extraordinary concern” regarding potential interactions of militarily relevant drugs, biologics, and chemicals, but recognized that published scientific literature is limited and that additional study is required.

4.4.18.4 Accidents and Incidents

The activities, procedures, and operations used in handling etiologic agents in JVAP activities during the production and testing of vaccines and toxoids are consistent with those examined in the BDRP FPEIS. In that evaluation, the likelihood of escape and survival of infectious agents outside of a facility, such as the site where JVAP activities will occur was considered, using Maximum Credible Event (MCE) methodologies [BDRP FPEIS (Appendix 9)]. MCEs are considered worst case events which realistically might occur, although the probability of such events is very low.

Although the BDRP FPEIS evaluated MCEs applicable to RDT&E activities and planned activities for the JVAP include large-scale production, the MCEs considered in the BDRP FPEIS apply. The amount of virulent (capable of causing disease) organisms used in the production of

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vaccines in the JVAP will not differ quantitatively from the amounts evaluated in the BDRP FPEIS. At the point in the vaccine production process when large suspensions of biological materials (e.g., 100 liters) are being produced, avirulent (not capable of causing disease) strains will normally be used.

The MCE for botulinum toxin described in the BDRP FPEIS is applicable to activities planned under the JVAP. The quantities of toxin which were considered in the BDRP FPEIS are comparable to the amounts which will be used in the JVAP activities. It is extremely unlikely that etiologic agents will be released to the environment from a site of JVAP execution. Redundant containment and safety procedures minimize risks to the public and workforce. MCEs including aerosol release, escape of an infected rodent, terrorist act, disgruntled employee, and unexpected external events were examined in the BDRP FPEIS and found to pose only a negligible risk. Because the assumption for these MCEs regarding the quantities of etiologic agents are directly comparable to the JVAP activities, it is concluded that risks to the public and the workforce from JVAP activities are very small.

4.4.19 Consequences of JVAP Actions Abroad

Executive Order 12114, *Environmental Effects Abroad of Major Federal Actions*, directs both the DA and the FDA to consider the environmental effects of their actions abroad. A REC has been prepared for the JVAP activities conducted at Porton International and is on file with the U.S. Army Medical Research and Materiel Command (USAMRMC). Executive Order 12114 also directs the FDA to consider the environmental effects of approving drug product applications on the environment outside the U.S. It is the responsibility of the company official at each of the foreign facilities to certify to the FDA that the manufacturing facilities comply with all local and national environmental laws; comply with the emission requirements of their permits; and the approval and/or subsequent increase in production at the facility is not expected to affect compliance with its existing emissions requirements or compliance with environmental laws.

4.4.20 Cumulative Impacts

The CEQ regulations implementing NEPA define cumulative impacts to the environment as those effects resulting from the impact of the proposed action when combined with past, present, and future actions (40 CFR § 1508.7). Thus, cumulative impacts are the sum of all direct and indirect impacts, both adverse and positive, that result from the incremental impacts of the action when added to other past, present, and reasonably foreseeable future actions regardless of source. Cumulative impacts may be accrued over time and/or impacts in conjunction with other pre-existing effects from other activities in the area (40 CFR § 1508.25).

Based on previous NEPA analyses conducted on similar and identical activities in a variety of environmental settings and on the data shown in Tables 4-2, 4-3, and 4-4, there is no indication that significant negative cumulative impacts will result from the proposed action, including both

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TABLE 4-2. SUMMARY CHARACTERIZATION OF ENVIRONMENTAL IMPACTS AT BIOMEDICAL SITES CONDUCTING ACTIVITIES SIMILAR TO THE JVAP

Environmental Attributes	Biomedical Sites						
	BDRP	USAMRIID	MDPH	TSI-GSD	WRAIR	Battelle	USARMICD
Plant & Animal Ecology	Negligible	Negligible	Negligible	Negligible	Negligible	Negligible	Negligible
Land Use	Negligible	Minor Negative	Minor Negative	Minor Negative	Minor Negative	Negligible	Minor Negative
Environmental Justice*							
Surface Water	Minor Negative	Minor Negative	Minor Negative	Minor Negative	Minor Negative	Minor Negative	Minor Negative
Groundwater	Negligible	Negligible	Negligible	Minor Negative	Negligible	Minor Negative	Negligible
Geology	Negligible	Negligible	Minor Negative	Negligible	Negligible	Negligible	Negligible
Historical & Cultural Resources	Negligible	Negligible	Negligible	Negligible	Negligible	Negligible	Negligible
Agriculture	Negligible	Negligible	Negligible	Negligible	Negligible	Negligible	Negligible
Climate	Negligible	Negligible	Negligible	Negligible	Negligible	Negligible	Negligible
Energy Resources	Negligible	Minor Negative	Minor Negative	Minor Negative	Minor Negative	Minor Negative	Negligible
Noise	Negligible	Negligible	Minor Negative	Minor Negative	Minor Negative	Negligible	Minor Negative
Odors	Minor Negative	Negligible	Negligible	Minor Negative	Minor Negative	Negligible	Minor Negative
Socioeconomic Environment	Minor Positive	Minor Positive	Minor Positive	Minor Positive	Minor Positive	Minor Positive	Minor Positive
Transportation	Negligible	Minor Negative	Negligible	Negligible	Minor Negative	Negligible	Negligible
Air Quality	Minor Negative	Minor Negative	Minor Negative	Minor Negative	Minor Negative	Minor Negative	Minor Negative
Public Opinion	Minor Negative	Minor Negative	Negligible	Negligible	Negligible	Negligible	Negligible
Program Benefits	Significant Positive	Significant Positive	Significant Positive	Significant Positive	Significant Positive	Significant Positive	Significant Positive
Human Health & Safety							
Public Health & Safety	Negligible	Negligible	Negligible	Negligible	Negligible	Negligible	Negligible
Worker Health & Safety	Minor Negative	Minor Negative	Minor Negative	Minor Negative	Minor Negative	Negligible	Minor Negative
Accidents & Incidents	Negligible	Negligible	Negligible	Minor Negative	Minor Negative	Negligible	Minor Negative
Cumulative Impacts	Minor Negative	Minor Negative	Minor Negative	Negligible	Minor Negative	Negligible	Negligible

* Although the environmental attribute, Environmental Justice, has not been previously assessed, it has not been reported as a program-related problem at existing sites.

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TABLE 4-3. SUMMARY OF POTENTIAL ENVIRONMENTAL IMPACTS OF THE JVAP

Environmental Attributes	Potential Environmental Impacts
Plant & Animal Ecology	Although potential impacts to plant and animal resources could occur from JVAP activities involving waste stream management, potential impacts will be mitigated by adherence to regulations regarding protection of wildlife and waste disposal.
Land Use	It is not anticipated that land use will be negatively impacted by JVAP operations. Execution of JVAP activities is likely to conform to existing land use patterns since activities will be conducted in existing facilities and new construction is not required.
Environmental Justice	No adverse impacts to minority or low-income populations are anticipated to result from current or planned JVAP activities. Each JVAP site will be evaluated to determine if the proposed action will affect minority or low-income population.
Surface Water	JVAP activities could potentially impact surface water quality if wastewater is discharged without adequate treatment. Potential negative impacts to surface water resources will be mitigated by adherence to wastewater treatment regulations and the use of prescribed methods of handling, use, and disposal of etiologic agents which neutralize toxins and render microorganisms harmless prior to entry into the waste stream. Wetlands would not be impacted since wastewater is only rarely discharged to a wetland.
Groundwater	The potential for JVAP activities to impact groundwater resources is very low; however, leaks from underground storage tanks and leaking sewage pipes are potential impacts. Compliance with regulations designed to protect groundwater resources will mitigate or eliminate significant impacts to groundwater at JVAP sites.
Geology	It is unlikely that the conduct of the JVAP will negatively impact geological resources because new construction or extensive renovation is not planned.
Historical & Cultural Resources	The potential for JVAP activities to impact historical or cultural resources would be determined by the proximity of JVAP sites to significant sites. Where significant historical and/or archaeological resources are present, adherence to applicable regulations has fully mitigated negative impacts.
Agriculture	Agricultural resources are unlikely to be impacted because new construction is not required by the JVAP.
Climate	JVAP activities could impact air quality and climate by increasing pollution through several pathways including energy consumption, commuting workforce, incineration, and air exhaust from biomedical laboratories. This adverse impact is likely to be minor.
Energy Resources	The conduct of JVAP activities will likely consume greater quantities of electricity per square foot than non-containment facilities but this is unlikely to adversely impact air quality.
Noise	Noise levels resulting from activities at JVAP sites will be evaluated on a site-by-site basis to determine the potential negative impacts on humans and ecological resources and necessary mitigation measures. Impacts from noise are likely to be negligible.
Odors	Unpleasant odors may result from the sterilization of JVAP waste material. However, these odors are transitory and rapidly diluted in the atmosphere. Adherence to applicable regulations governing the disposal of wastes will mitigate the minor impact to the local environment.
Socioeconomic Environment	Conduct of the JVAP may result in a minor positive impact on the local economy at each JVAP site.
Transportation	It is not anticipated that the JVAP will significantly impact transportation resources because JVAP activities will be conducted at existing sites and are unlikely to significantly add to existing traffic burdens. Potential impacts to transportation will be evaluated on a site-by-site basis in accordance with guidance provided in NEPA and AR 200-2.

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Environmental Attributes	Potential Environmental Impacts
Air Quality	The impacts of JVAP activities on local air quality are likely to be minor. Potential impacts on air quality resulting from increased pollution from energy consumption, commuting workforce, incineration activities, and air exhaust from biomedical laboratories will be mitigated by adherence to the CAA and CDC/NIH guidelines. The impacts of JVAP activities on local air quality will be evaluated on a site-by-site basis.
Public Opinion	The production of biological defense vaccines is controversial because of the perceived potential for this research to be used for offensive purposes. In addition, public concerns may entail questions about the effectiveness of biological defense vaccines; distrust of the military; the use of soldiers as research subjects; informed consent of soldiers; the use of recombinant DNA and engineered microorganisms; and whether the military should be involved in vaccine production.
Program Benefits	Biological defense vaccines protect service men and women against morbidity and mortality resulting from the hostile use of biological warfare agents. They also protect personnel engaged in biological defense research activities with potential risk of exposure to these agents. The JVAP creates an integrated approach to vaccine development, production, and fielding focused on obtaining FDA licensure for all products.
Human Health & Safety	
Public Health & Safety	JVAP activities are not likely to pose a significant threat to public health and safety because of the use of carefully considered safety/containment procedures and practices. Further, decontamination of all potentially infectious wastes prior to discharge prevents the release of infectious agents to the environment.
Worker Health & Safety	Workers engaged in biological defense research activities risk exposure to etiologic agents. The actual risk to the JVAP workforce of contracting disease is small and is further ameliorated by vaccination when available, redundant safety equipment, procedures, and training. Compliance with laws and regulations promulgated for worker safety by Federal, DoD, DA, and state agencies will ensure the impacts to worker safety will be minor.
Health & Safety of Vaccine Recipients	As with "conventional" vaccines, there are potential risks associated with the administration of biological defense vaccines. Risks to vaccine recipients vary with each vaccine. Individuals also vary in their responses to vaccines. Compliance with FDA and other applicable regulations and the monitoring of vaccine recipients will minimize adverse impacts of vaccination.
Accidents & Incidents	It is extremely unlikely that etiologic agents will be released to the environment from a site of JVAP execution. Redundant containment and safety procedures minimize risks to the public and workforce. MCEs including aerosol release, escape of an infected rodent, terrorist act, disgruntled employee, and unexpected external events were examined in the BDRP FPEIS and found to pose only a negligible risk. Because the assumption for these MCEs regarding the quantities of etiologic agents are directly comparable to the JVAP activities, it is concluded that risks to the public and the workforce from JVAP activities are very small.
Consequences of JVAP Actions Abroad	A Record of Environmental Consideration (REC) has been prepared for the JVAP activities conducted at Porton International. It is the responsibility of the company official to certify to the FDA that the manufacturing facilities comply with all local and national environmental laws; comply with the emission requirements of their permits; and approval and/or subsequent increase in production at the facility is not expected to affect compliance with its existing emissions requirements or compliance with environmental laws.
Interactive Effects of Vaccines & Other Agents	The health of the recipient population and the lead time for observing adverse health effects minimize the potential for adverse impacts. Additionally, should there be adverse impacts, effects would be restricted to the recipient with minimal or no potential for adverse impacts in the larger population.
Cumulative Impacts	Significant adverse cumulative impacts are not anticipated from the implementation of the proposed action.

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TABLE 4-4. COMPARISON OF THE POTENTIAL ENVIRONMENTAL IMPACTS OF THE PROPOSED ACTION AND THE ALTERNATIVES

Environmental Attributes	<u>Alternative I</u> Continue Current & Currently Planned JVAP Operations	<u>Alternative II</u> Cease Current & Currently Planned JVAP Operations (No action)	<u>Alternative III</u> Conduct JVAP Current & Currently Planned Operations in a Consolidated Government Facility	<u>Alternative IV</u> Conduct JVAP Current & Currently Planned Operations in a Consolidated Contractor Facility
Plant & Animal Ecology	Negligible	Negligible	Negligible	Negligible
Land Use	Negligible	Negligible	Negligible	Negligible
Environmental Justice	Negligible	Negligible	Negligible	Negligible
Surface Water	Minor Negative	Negligible	Minor Negative	Minor Negative
Groundwater	Negligible	Negligible	Negligible	Negligible
Geology	Negligible	Negligible	Negligible	Negligible
Historical & Cultural Resources	Negligible	Negligible	Negligible	Negligible
Agriculture	Negligible	Negligible	Negligible	Negligible
Climate	Negligible	Negligible	Negligible	Negligible
Energy Resources	Minor Negative	Negligible	Minor Negative	Minor Negative
Noise	Negligible	Negligible	Minor Negative	Minor Negative
Odors	Minor Negative	Negligible	Minor Negative	Minor Negative
Socioeconomic Environment	Minor Positive	Negligible	Minor Positive	Minor Positive
Transportation	Minor Negative	Negligible	Minor Negative	Minor Negative
Air Quality	Minor Negative	Negligible	Minor Negative	Minor Negative
Public Opinion	Minor Negative	Negligible	Minor Negative	Minor Negative
Program Benefits	Significant Positive	Significant Negative	Significant Positive	Significant Positive
Human Health & Safety				
Public Health & Safety	Negligible	Negligible	Negligible	Negligible
Worker Health & Safety	Minor Negative	Negligible	Minor Negative	Minor Negative
Accidents & Incidents	Negligible	Negligible	Negligible	Negligible
Cumulative Impacts	Minor Negative	Negligible	Minor Negative	Minor Negative

impacts over time and in conjunction with other activities in the area (BDRP FPEIS, 1989; Battelle EA, 1993; MDPH EA, 1993; TSI-GSD EA, 1992; USAMRIID EA, 1991). Cumulative impacts in relation to past, present, and future actions at JVAP sites cannot be fully evaluated at this time because this analysis requires the use of site-specific data. However, since activities qualitatively and quantitatively similar to the actions which will be taken under the JVAP have been performed at some geographical locations for more than 30 years without evidence of adverse cumulative impacts to the environment (MDPH EA, 1993; TSI-GSD EA, 1992; USAMRIID EA, 1991), it is unlikely that cumulative impacts will result from implementation of the proposed action. Potential adverse cumulative impacts associated with Alternative III (Consolidated Government Facility) or Alternative IV (Consolidated Contractor Facility) would be greater because of the consolidation of program activities, including waste disposal, at one geographical location. No cumulative impacts would result from the implementation of the no action alternative.

4.5 COMPARISON OF THE PROPOSED ACTION AND THE ALTERNATIVES

No significant environmental impacts are anticipated with implementation of the proposed action. As detailed in Section 4.4.1 through Section 4.4.20 and summarized in Table 4-2, activities similar or identical to those which will be performed under the JVAP have not resulted in significant adverse impacts to the environment. Detailed, site-specific assessments indicate

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that adverse impacts associated with the conduct of these activities are limited to very minor and negligible consequences over a broad range of environmental settings. Because the qualitative and quantitative aspects of the JVAP as well as the operational, safety, and regulatory constraints are so similar to the comparative sites discussed in Section 4.4, it is concluded that the environmental impacts of JVAP activities also will likely be similar. The most severe adverse impacts will likely be minor, and will be related primarily to waste disposal operations (see Table 4-3).

The probable environmental impacts resulting from implementation of the alternatives do not differ significantly from the proposed action (see Table 4-4). Implementation of Alternative III (Consolidated Government Facility) or Alternative IV (Consolidated Contractor Facility) will not cause significant adverse impacts to the environment. However, the consolidation of JVAP activities at one geographical location will tend to concentrate these minor negative impacts, potentially causing minor cumulative impacts at that location. Implementation of the no action alternative would eliminate the minor adverse impacts associated with implementation of the other three options.

4.5.1 Alternative I: Continue Current and Currently Planned JVAP Operations (Preferred Alternative)

This alternative entails continuing the JVAP as currently planned and conducted. The DoD Mission Needs Statement for Biological Defense articulates the importance of medical biological defense products to military readiness. The current and currently planned activities of the JVAP will provide methods for the development and acquisition of vaccines for Joint and Service-unique requirements as the Deputy Secretary of Defense has directed, through a prime systems contract with oversight by the Defense Acquisition Board. Under this program, the JPM will be the principal advocate and single point of contact for all biological defense detection and vaccine acquisition efforts. The JPM will provide centralized management of assigned medical and non-medical programs to expedite materiel solutions for validated deficiencies in biological defense, and monitor biological defense technology-based activities.

Implementing the proposed action will allow the DA to benefit from currently licensed biological defense vaccines such as anthrax without purchasing the associated proprietary technology. It will also enable the government to use the experience and expertise of both workers and establishments that have been engaged in activities related to biological defense vaccines. Significant management, regulatory affairs, and production challenges are associated with this program because of the number of different biological defense products included. Contract(s) will be awarded under this program to create a single integrator/manager to develop and implement a plan for vaccine life-cycle management and to focus its scientific/regulatory expertise, management oversight, and physical resources to meet DoD requirements.

The use of unproven technology or more hazardous organisms than those already used in vaccine development activities and testing activities or already used in current vaccine production for infectious diseases is not expected. A vaccine-specific EA will be conducted by the DoD for

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review by FDA and the public in the event that a vaccine candidate does not qualify for categorical exclusion. As discussed in detail in Section 4.4, anticipated environmental impacts associated with implementing the proposed action are minor.

Current and currently planned JVAP activities are and will be conducted at existing facilities already engaged in the conduct of identical or similar activities. Analyses of activities at existing facilities engaged in RDT&E and production of biological defense vaccines concluded that there was minimal potential for adverse impact to either human health or the environment (BDRP FPEIS, 1989; USAMRIID EA, 1991; MDPH EA, 1993; TSI-GSD EA, 1992; WRAIR EA, 1993; Battelle EA, 1993; USAMRICD EA, 1992). Should substantive changes in the operation or implementation of the proposed action occur, these changes will be analyzed in the context of NEPA. This option is the only alternative which meets the needs of the national defense. Therefore, operation of the JVAP in its planned scope is considered the preferred alternative.

4.5.2 Alternative II: Cease Current and Currently Planned JVAP Operations (No Action Alternative)

The no action alternative is to cease currently conducted and planned activities associated with vaccine production for the DoD. Implementation of this alternative could severely curtail or terminate the Medical Biological Defense Research Program. There are no adverse environmental impacts associated with the no action alternative.

The no action alternative is not preferred because it will neither address nor meet DoD requirements to protect service men and women from biological warfare agents. It is unlikely that sufficient, if any, FDA licensed vaccines would be available from stockpiled supplies or for direct purchase in the event that they are needed for protection of service men and women as was the case with the Gulf War.

4.5.3 Alternative III: Conduct Current and Currently Planned JVAP Operations in a Consolidated Government Facility

The implementation of Alternative III would require the renovation of existing facilities or construction of new facilities rather than using existing, operational facilities. It has been estimated that construction of a dedicated biological defense vaccine facility would cost in excess of \$100 million. Costs required to renovate an existing facility have been estimated to perhaps equal to or exceed costs of new construction.

The negligible environmental impacts of Alternative III would not be expected to differ significantly from those of the proposed action and preferred alternative. If the operation was sited in one facility, there would be minor positive impacts to the local community economy associated with construction and/or renovation which would not be manifested by the use of existing facilities. Operations at a single site would concentrate the adverse impacts resulting from use of natural resources, waste stream outflows and burdens to local wastewater processing

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plants, and/or water treatment facilities. It is likely that the construction of a new dedicated facility would also require the construction of a dedicated incinerator. Substantial renovations or new construction would likely delay the availability of FDA-licensed vaccines and continue the current biological warfare threat to U.S. forces.

4.5.4 Alternative IV: Conduct Current and Currently Planned JVAP Operations in a Consolidated Contractor Facility

This alternative is similar to Alternative III except that contractor personnel, non-DoD personnel, would staff the program. The program would be conducted in unspecified privately owned facilities.

The negligible environmental impacts of Alternative IV would not be significantly different from those of the proposed action and preferred alternative. If the consolidated contractor facility were sited in one location, there would be minor positive impacts to the local community economy associated with construction and/or renovation which would not be manifested by the use of existing facilities. A consolidated contractor operation at a single site would concentrate the impacts resulting from use of natural resources, and waste stream outflows to one geographical location which may result in impacts to local wastewater processing plants or water treatment facilities. It is likely that the construction of a new dedicated facility would also require the construction of a dedicated incinerator. As with Alternative III, this Alternative would likely delay the availability of FDA-licensed vaccines to protect U.S. military forces from potential biological warfare threats.

5.0 CONCLUSIONS

The principal conclusions of this PEA are (1) conducting the JVAP in its current and planned scope (Alternative I, the preferred alternative) has not and is not expected to result in significant adverse environmental impacts and will result in important benefits to the U.S. by protecting armed forces personnel from potential death and disease resulting from exposure to biological warfare agents; (2) discontinuing current and currently planned JVAP activities, the no-action alternative (Alternative II), will not meet identified needs with respect to biological defense as identified in national defense policy; (3) conducting JVAP current and currently planned operations in a consolidated government facility (Alternative III) or in a consolidated contractor facility (Alternative IV) would likely require construction of new facilities or renovations to existing facilities; and (4) neither the proposed action nor any of the alternatives are likely to cause significant adverse environmental impacts.

Current and proposed JVAP activities have been (prior to JPO BD establishment and under a different management organization) and will continue to be performed without significant environmental impacts. The most severe potential effects associated with JVAP activities are predicted to be minor, and to date, any observed effects have been insignificant. Potential risks to JVAP laboratory and production workers, public health, and the environment are and will be mitigated by the application of required work practice and engineering controls which direct the safe handling, use and disposal of etiologic agents and other potentially hazardous materials.

Joint Vaccine Acquisition Program product safety and effectiveness are and will be regulated and enforced by the FDA. Adherence to FDA regulatory requirements for development, production, storage, testing, and use of JVAP products will minimize risks to JVAP vaccine recipients. Recipients of JVAP products will be further protected by the application of required preventive medicine practices, state-of-the-art medical care, and the implementation of data management approaches for long-term medical follow-up.

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7.0 PERSONS AND AGENCIES CONSULTED

Steven Bieber	Maryland Department of the Environment	(410) 631-3000
Walter Busbee	JPO BD	(703) 681-9678
Robert Carton	USAMRMC	(301) 619 2004
Ray Clark	CEQ, Associate Director of NEPA Oversight	(202) 395-5750
William Cohen	Department of Justice	(202) 305-0423
LTC David Danley	JPO BD	(703) 681-9600
David Evans	OSD (CBM)	(703) 602-5620
Winifrede Fanelli	JPO BD	(703) 681-9648
Kenneth W. Holt	DHHS/National Center for Environmental Health	(770) 488-7074
COL Gary Hurst	CBM	(703) 602-5620
Timothy Julius	HQDA, Environment	(703) 693-0543
Mary Malarkey	Establishment Licensing Center for Biologics Evaluation and Research, FDA	(301) 827-3031
Stephanie May	U.S. Army, General Counsel	(703) 693-3664
LtCol Roy Salomon	DUSD (ES)	(703) 604-1628
Richard E. Sanderson	EPA/Office of Federal Activities/Enforcement and Compliance Issues	(202) 564-7148
Craig Teller	U. S. Army, General Counsel	(703) 693-3024
James Van Ness	OSD/CDGC (E&I)	(703) 693-4841
Lewis D. Walker	SAIC	(703) 318-4542
Karl Weiss	DUSD (ES)	(703) 604-1846

8.0 PREPARERS

The following personnel, under a USAMRMC contract to Science Applications International Corporation (DAMD17-93-C3141), provided instrumental technical assistance to the Joint Program Office for Biological Defense in the preparation of this Programmatic Environmental Assessment.

Preparers:

Beth A. Schaberg
M.S., Biology, Cleveland State University
Beaver Schaberg Associates, Cleveland, Ohio

John R. Beaver
Ph.D., Environmental Engineering Sciences, University of Florida
Beaver Schaberg Associates, Cleveland, Ohio

Daniel L. Rickett
Ph.D., Psychology, University of Missouri-Columbia
Science Applications International Corporation, Frederick, Maryland

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9.0 LIST OF ACRONYMS

AAALAC	Association for Assessment and Accreditation of Laboratory Animal Care
ABLs	Animal Biosafety Levels
ACGIH	American Conference of Governmental Industrial Hygienists
AR	Army Regulation
BD	Biological Defense
BDRP	Biological Defense Research Program
BDRP FPEIS	Biological Defense Research Program Final Programmatic Environmental Impact Statement
BL	Biosafety Levels
BW	Biological Warfare
CAA	Clean Air Act
CBER	Center for Biologics Evaluation and Research
CDC	Centers for Disease Control and Prevention
CEQ	Council on Environmental Quality
CFR	Code of Federal Regulations
cGMP	Current Good Manufacturing Practices
CHP	Chemical Hygiene Plan
CO	Carbon Monoxide
CWA	Clean Water Act
DA	Department of the Army
DAB	Defense Acquisition Board
DAE	Defense Acquisition Executive
DHHS	Department of Health and Human Services
DNA	Deoxyribonucleic Acid
DoD	Department of Defense
DOT	Department of Transportation
EA	Environmental Assessment
EEE	Eastern Equine Encephalitis
EIS	Environmental Impact Statement
ELA	Establishment License Application
EO	Executive Order
EPA	Environmental Protection Agency
EPAct	Energy Policy Act
FAR	Federal Acquisition Regulations
FDA	Food and Drug Administration
FONSI	Finding of No Significant Impact
FPEIS	Final Programmatic Environmental Impact Statement
GLP	Good Laboratory Practices
HAPs	Hazardous Air Pollutants
HEPA	High Efficiency Particulate Air

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IND	Investigational New Drug
IPR	In-Process Review
IPT	Integrated Product Teams
JCS	Joint Chiefs of Staff
JPM	Joint Program Manager
JPM BD	Joint Program Manager for Biological Defense
JPO	Joint Program Office
JPO BD	Joint Program Office for Biological Defense
JVAP	Joint Vaccine Acquisition Program
JVAP IND	Joint Vaccine Acquisition Program Investigational New Drug
JVAP RFP	Joint Vaccine Acquisition Program Request for Proposal
LS	Large Scale
LSS	Laboratory Sewer System
MBPI	Michigan Biologic Products Institute
MCEs	Maximum Credible Events
MDA	Milestone Decision Authority
MDPH	Michigan Department of Public Health
MSDS	Materiel Safety Data Sheets
MSI	Milestone I
MSII	Milestone II
MSIII	Milestone III
NAAQS	National Ambient Air Quality Standards
NDA	New Drug Application
NEC	National Electrical Code
NEPA	National Environmental Policy Act
NFPA	National Fire Protection Association
NIH	National Institutes of Health
NOI	Notice of Intent
NOx	Nitrogen Oxide
NPDES	National Pollutant Discharge Elimination System
NRC	Nuclear Regulatory Committee
OSHA	Occupational Safety and Health Administration
OTA	Office of Technology Assessment
PADER	Pennsylvania Department of Environmental Resources
PEA	Programmatic Environmental Assessment
PELs	Permissible Exposure Limits
PLA	Product License Application
PMO	Program Management Office
RCRA	Resource Conservation and Recovery Act
RDA	Research, Development and Acquisition
RDT&E	Research, Development, Testing & Evaluation
REC	Record of Environmental Consideration
RFP	Request for Proposals

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RMW	Regulated Medical Waste
RSO	Radiation Safety Officer
SAIC	Science Applications International Corporation
SARA	Superfund Amendments and Reauthorization Act
SDWA	Safe Drinking Water Act
SHPO	State Historic Preservation Officer
SO ₂	Sulfur Dioxide
TSI-GSD	The Salk Institute - Government Services Division
UNSCOM	UN Special Commission
USAMMA	U.S. Army Medical Materiel Agency
USAMMDA	U.S. Army Medical Materiel Development Activity
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRICD	U.S. Army Medical Research Institute of Chemical Defense
USAMRIID	U.S. Army Medical Research Institute of Infectious Diseases
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	U.S. Code
USDA	U.S. Department of Agriculture
VAERS	Vaccine Adverse Event Reporting System
VEE	Venezuelan Equine Encephalitis
VOCs	Volatile Organic Compounds
WEE	Western Equine Encephalitis
WRAIR	Walter Reed Army Institute of Research

APPENDIX A

BIOLOGICAL WARFARE

Introduction

The DoD must provide U.S. forces with reasonable levels of protection against battle and non-battle threats to their health and well being. Protection from BW agents has received increased attention since the Gulf War. Medical protective countermeasures, such as vaccines, are affordable, safe, and effective ways to protect the health and lives of U.S. service men and women against a BW agent attack. Vaccines may be administered well in advance of deployment to areas where there is a high threat of BW agent attack. Vaccines, unlike physical protective devices such as gas masks, require no warning or detection of a BW attack to provide protection. Vaccine induced immunity to BW agents requires no maintenance beyond necessary boosters and can be in-place and working around the clock. The JPO BD is responsible for the development and acquisition of safe, effective vaccines and related medical materiel for protection of U.S. forces from BW attack. The JPO BD discharges this responsibility through the JVAP.

The BW Threat

Biological warfare is the use of pathogens or toxins against humans, animals, plants, or materiel for hostile purposes. Pathogens are disease-causing microorganisms (e.g., bacteria, fungi, viruses) and toxins are poisons that originate from the biological activity of living organisms (e.g., plants, fungi, microorganisms, vertebrates, invertebrates). Since at least 600 B.C. naturally occurring pathogens and toxins have been used as weapons (see Table A-1). Some biochemicals that normally serve as regulators of body functions (bioregulatory and biomodulatory molecules or physiologically active compounds) also have the potential to be used as BW agents. Higher than normal concentrations of such biochemicals can cause disease.

TABLE A-1. HISTORICAL SUMMARY OF BW WEAPONS DEVELOPMENT, USE, AND PROHIBITION

Date	Summary
600 BC	<ul style="list-style-type: none">• Solon, King of Athens, contaminated his enemies' drinking water supplies with roots of the hellebore plant.• Assyrians used rye ergot to poison water wells.
190 BC	<ul style="list-style-type: none">• In the Battle of Eurymedon, Hannibal fired earthen vessels full of venomous snakes into the ships of King Eumenes.
1346	<ul style="list-style-type: none">• The Tartar Army cast the bodies of plague fatalities over the city walls of Kaffa (now Feodosia). Some historians believe this led to the great pandemic of Europe.
1527	<ul style="list-style-type: none">• Pizarro used smallpox-contaminated clothing to spread disease among the Incas, in the Spanish conquest of Peru.

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Date	Summary
1675	<ul style="list-style-type: none"> Article 57 of the Strasbourg Agreement of August 27 documented an agreement between the French and German Armies not to use poison bullets. This was the first international agreement in modern history prohibiting the use of such weapons.
1710	<ul style="list-style-type: none"> The Russian Army is said to have used cadavers of plague victims to provoke an epidemic among the Swedes.
1763	<ul style="list-style-type: none"> In the North American French and Indian War, the English gave Native Americans (loyal to the French) smallpox-contaminated blankets and created an epidemic that decimated the Indians.
1797	<ul style="list-style-type: none"> In his Italian campaign, Napoleon attempted to infect the city of Mantura with Swamp Fever.
1863	<ul style="list-style-type: none"> In the American Civil War, General Johnson used bodies of sheep and pigs to pollute drinking water at the city of Vicksburg.
1874	<ul style="list-style-type: none"> The Conference of Brussels produced an agreement prohibiting the use of poisonous weapons.
1915-1917	<ul style="list-style-type: none"> In World War I, the Germans are suspected of: using cholera in Italy and plague in St. Petersburg; inoculating horses and cattle with glanders before shipment from the U.S. to France; using glanders and anthrax to infect horses and cattle in Bucharest; using glanders to infect 4,500 mules in Mesopotamia; and other related incidents that Germany denied.
1925	<ul style="list-style-type: none"> The Geneva Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or other Gases, and of Bacteriological Methods of Warfare was established, prohibiting the use of chemical or biological agents or methods of warfare in war.
1937-1945	<ul style="list-style-type: none"> In the World War II era, the Japanese initiated an ambitious biological weapons program. The program was terminated and the laboratory facilities of Unit 731 were destroyed by fire in 1945. During this period, the Japanese made use of various biological agents, including plague and anthrax, to contaminate regions and cities. Epidemics were often started and frequently re-emerged in regions where the diseases had not been previously recorded; in at least one instance Japanese troops suffered large losses from Japan's use of BW agents.
1941	<ul style="list-style-type: none"> The U.S. initiated an offensive and defensive BW program; the offensive program was terminated in 1969. The program was driven by a policy of deterrence backed by a capability to retaliate in kind. The program was deemed necessary because of suspicions that BW weapons were being developed by Germany and Japan in WWII era (NB: Hitler forbade the development of BW weapons), and subsequently, by the Soviet Union.

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Date	Summary
1942	<ul style="list-style-type: none"> The British conducted a number of experiments on Gruinard Island, Scotland, to measure the effects of anthrax. Sheep were tethered in position and bombs containing anthrax spores were dropped from planes. Some of the dead sheep later washed up on the shore of the Scottish mainland and precipitated an anthrax outbreak. Despite extensive burning and fire bombing, the island remained contaminated for many years.
1969	<ul style="list-style-type: none"> President Richard Nixon unilaterally renounced the use of BW weapons and limited programs to defensive purposes only; toxins were included in 1970.
1972	<ul style="list-style-type: none"> The Biological and Toxin Weapons Convention was concluded, prohibiting signatories from developing, producing, or stockpiling bacteriological (biological) and toxin weapons. The Convention was ratified in 1975.
1972	<ul style="list-style-type: none"> In Missouri, a fascist group called the Order of the Rising Sun was found in possession of 30 to 40 kg of typhoid bacteria cultures that they planned to use in the water supplies of midwestern U.S. cities.
1975	<ul style="list-style-type: none"> Soviet-backed Vietnamese and Pathet Laos forces were suspected of using planes and helicopters to deliver aerosol “yellow rain” tricothecene toxins in Laos, Cambodia and Afghan the mid-to-late 1970s.
1978	<ul style="list-style-type: none"> In a case of state-sponsored terrorism, a Bulgarian exile died after being stabbed with an umbrella tip that delivered a tiny steel ball which had been cross-drilled, and filled with ricin toxin.
1979	<ul style="list-style-type: none"> A massive biological weapons accident occurred near Sverdlovsk, Russia. An explosion in a military facility released anthrax spores that resulted in 100 to 1,000 fatalities from pulmonary anthrax.
1986	<ul style="list-style-type: none"> The Rajneesh cult was accused of contaminating salad bars with salmonella to influence a local election in Antelope, Oregon; 750 salmonella poisoning cases were reported.
1989	<ul style="list-style-type: none"> The Bader Meinhof gang was found to have <i>Clostridium botulinum</i> cultures in a home laboratory located in Paris.
1991	<ul style="list-style-type: none"> Iraqi officials admitted to United Nations inspectors that Iraq had engaged in offensive biological weapons research that had been initiated in 1979.
1995	<ul style="list-style-type: none"> In Japan, the Sacred Truth/Doomsday cult was reported to have cultures of biological agents. These were found during raids of their compounds, which included facilities for manufacturing lethal chemical agents, following the cult’s release of sarin in the Tokyo subway system.

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Date	Summary
1995	<ul style="list-style-type: none">• Iraqi officials admitted to having had large stockpiles of offensive BW agents (botulinum toxin and anthrax) before the Gulf War; they said the stocks were destroyed to prevent their dissemination from storage sites as a result of coalition forces' bombing.

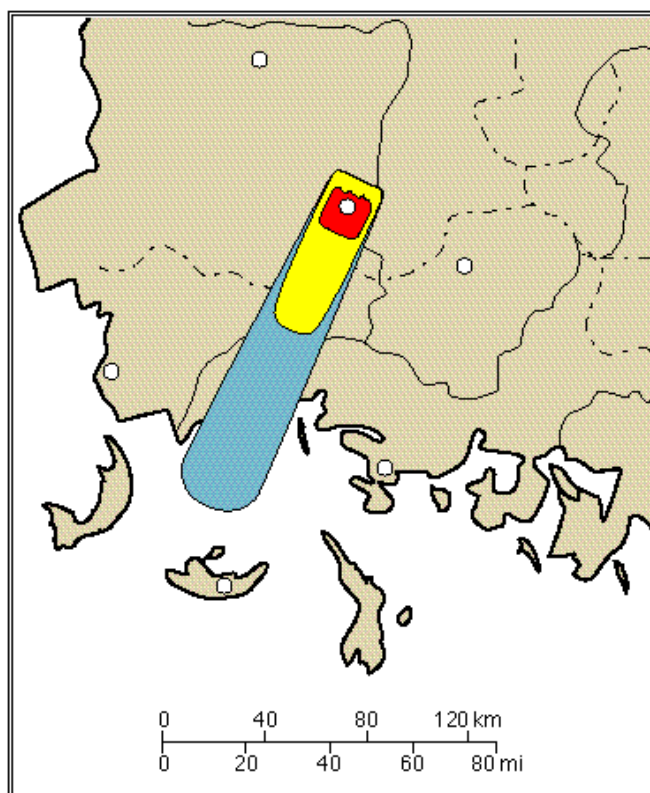
Advances in biotechnology are widespread and readily available throughout the world. Such advances make it possible to modify naturally occurring pathogens and toxins and to amplify desirable characteristics for their use as BW agents. These kinds of characteristics include large-scale, high-yield agent producibility; increased agent survival under natural conditions (e.g., increased tolerance to extremes in temperature and humidity as well as resistance to ultraviolet light); increased virulence and infectivity; agent resistance to prevailing medical treatments (e.g., antibiotics); as well as increased resistance to accurate diagnosis, isolation or detection. Advances in biotechnology also make it easier to select for and to amplify desirable characteristics for applications in vaccine development and related medical materiel or other peaceful purposes.

BW agents can be delivered as either a wet or dry aerosol with relatively small amounts effectively covering potentially thousands of square kilometers. Delivery devices for BW agents include tactical ballistic missile submunitions or bulk release devices, aerial bomblets, aerial and point-source sprayers, and artillery submunitions. They can be delivered by saboteur or terrorist devices and by covert contamination of food, water supplies, and air handling systems. Exposure to exceptionally small doses of BW agent can lead to immediate (minutes for some toxins) or delayed (days for some bacteria and viruses) incapacitating and frequently fatal disease among unwarned and unprotected personnel. Appendix B lists the disease characteristics for a number of potential BW agents and definitive medical treatment, if any, to hasten recovery and prevent death.

A BW Threat Scenario

The following scenario serves to illustrate potential impacts of a modern BW agent attack. In this scenario a single tactical ballistic missile armed with 2000 submunitions filled with a total agent mass of 78 kilograms (kg) of dry *Bacillus anthracis*, the causative agent of anthrax, is used to attack an airbase. Modeling in this scenario assumes attack during wintertime meteorological conditions at 5:00 a.m. local time. As illustrated in Figure A-1, the resulting hazard footprint is defined by three contour boundaries. The footprint extends 140 kilometers (km) downwind from the airbase, across a port city, and almost to otherwise remote islands; the crosswind hazard extends approximately 25 km at the widest point. If a population within the hazard footprint is immunized prior to attack with the FDA-licensed anthrax vaccine, the attack would not break through the protection afforded by the vaccine. There would be no anthrax casualties. Conversely, in an unvaccinated population the innermost contour of the hazard footprint bounds an area where 50% or greater of the population would be expected to die, even with the timely administration of antibiotic therapy. The intermediate footprint contour bounds an area of

FIGURE A-1. BW ATTACK SCENARIO



hazard where 50% or greater of the population would be expected to die if they were without medical intervention or physical (i.e., gas mask) protection³. The outermost contour bounds an area of hazard where 5% or greater of the population would be expected to die if they were without medical or physical protection. This scenario demonstrates the potential of BW agents as strategic and operational WMD. Equally horrendous results could be expected from a terrorist attack with readily available sprayers or other dissemination devices in urban areas.

The Biological And Toxin Weapons Convention

In August 1971, the United States and the Soviet Union jointly fashioned a draft convention, the *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction*. This convention is often referred to as the Biological and Toxin Weapons Convention (BTWC) and represents the first multi-lateral agreement on elimination of an entire class of strategic WMD. The draft convention was approved by the United Nations (UN) General Assembly in December 1971 by a vote of 110

³ The effectiveness of physical protection is proportional to effective exclusion of BW agent and factors such as agent infectivity. Inhalation of small amounts of agent can be anticipated due to intermittent failures of the mask-to-face seal, poor fit, poor mask discipline, failures to detect BW agents, and time required to don protective equipment during a BW attack.

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to 0. President Ford signed the BTWC final ratification instruments on January 22, 1975 and the Convention entered into force on March 26, 1975.

The BTWC is of unlimited duration and States Parties to the BTWC agreed never, under any circumstances, to develop, produce, stockpile, retain, or acquire biological agents or toxins, their weapons systems, or the means for delivery for hostile purposes, or for other than peaceful purposes. They also agreed not to transfer BW capabilities or assist any other nation or group to acquire such capabilities. However, the BTWC has no verification provisions, such as unannounced inspections, that might provide some assurance of compliance with the convention. Verification is viewed by some as impractical, very expensive, and ineffective because industrial requirements for an offensive BW program are common to very widespread, legitimate industrial activities such as pharmaceutical manufacturing. Furthermore, on-site, highly intrusive and continuing monitoring would be very difficult to conduct while maintaining private industry needs for security of proprietary information, marketing strategies and alliances, and customer and supplier lists.

Six countries (i.e., Canada, France, Iraq, Russia, United Kingdom, and the United States) have admitted to having had offensive BW programs in the past. The number of States possessing or pursuing BW capabilities has increased and it has been reported that "...the number of countries known or suspected of having offensive biological weapons programs has tripled since the Biological and Toxin Weapons Convention was instituted in 1972, according to the Defense Intelligence Agency." Furthermore, the cost of acquiring a WMD capability (i.e., biological, chemical, nuclear) is proportional to the number of countries agreeing to prohibit that type of WMD. According to a report by the Office of Technology Assessment (OTA), there are approximately 188 countries in the world. Of these, only 125 countries have signed the BTWC and fewer have ratified it since 1972 when it was opened for signature (note that Iraq signed and ratified the BTWC). In contrast approximately 150 nations have signed the Nuclear Non-Proliferation Treaty and at least 140 are signatories to the Chemical Weapons Convention which was opened for signing in 1993. From analyses of open sources of information, including statements by U.S. Government officials, the OTA found that 15 countries have been reported as suspected of possessing biological weapons; the countries appearing on two-thirds of the reports are shown in Table A-2. Also shown in Table A-2 are those countries, as estimated by the Report of the Special Inquiry into the Chemical and Biological Threat of the Committee of the Armed Services, reported as potentially either possessing or capable of developing an offensive BW capability.

**TABLE A-2. COUNTRIES REPORTED AS POSSESSING OR PURSUING UNDECLARED
OFFENSIVE BW PROGRAMS**

GEOGRAPHICAL REGION	OFFICE OF TECHNOLOGY ASSESSMENT	HOUSE ARMED SERVICES COMMITTEE SPECIAL INQUIRY
Middle East	Iran Libya Iraq Syria	Egypt Israel Iran Libya

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GEOGRAPHICAL REGION	OFFICE OF TECHNOLOGY ASSESSMENT	HOUSE ARMED SERVICES COMMITTEE SPECIAL INQUIRY
	Israel	Iraq Syria
East Asia	China North Korea Taiwan	China North Korea Taiwan
Other		Cuba Former Soviet Union

The level of agreement between the two reports is striking, and although actual U.S. intelligence estimates may be different, the table serves to illustrate a potential threat of the use of BW agents against U.S. forces or allied and coalition partners. It is also noteworthy that the geographical regions represent areas of the world where tensions have been high and where the U.S. has substantial national interests.

Proliferation

Commercial growth and expansion related to biotechnology since the disestablishment of the U.S. offensive BW program in 1969 have changed the question, in many cases, from “does a particular state have a BW weapons production capability?” to “how sophisticated is a state’s BW production and weaponization capability?” Over the past 25+ years since the U.S. terminated its offensive BW programs, there have been substantial advances in bioprocess technologies and greatly improved, widespread availability and access to state-of-the-art biotechnology. The U.S. and Soviet BW technologies of the mid-1960s were sufficient to inflict mass casualties. It would be naive to believe that developing nations or terrorist organizations, whether independent or state-sponsored, cannot acquire and master 40-year-old technology. Furthermore, proliferation of BW capable states, as opposed to nuclear or chemical capable states, may be due to non-weapons-related technology considerations. Biotechnology is vastly lower in cost and requires substantially less of an identifiable, unique infrastructure and starting materials than either chemical weapons or nuclear weapons technologies. Finally, applications of biotechnology for BW purposes are much more deniable because of plausible and widespread dual-use for peaceful applications (e.g., food and beverage production, medical applications).

The recent Iraq experience illustrates the threat from the proliferation of BW capable states. Following the Gulf War, the UN Special Commission (UNSCOM) had highly intrusive access for verification of Iraqi WMD (nuclear, biological and chemical) and their strategic delivery systems. Despite unparalleled access over a 4-year period, it was not until Iraqi declarations in August 1995 that the world, through UNSCOM, began to recognize the magnitude and diversity of Iraq’s BW capabilities. Over a 5-year period beginning in 1985, Iraq’s BW program grew from a small research and development effort to large-scale production of a broad range of BW agents. This program included lethal (e.g., anthrax, botulinum toxin, ricin), incapacitating (e.g., aflatoxin, mycotoxins, hemorrhage conjunctivitis virus) and anti-crop (wheat cover smut) BW agents. Delivery systems developed by Iraq for BW purposes included tactical weapons (e.g., artillery

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shells, 122 mm rockets) and strategic weapons (e.g., aerial bombs, spray tanks, Al Hussein missile warheads). Effectiveness of these weapons was demonstrated in open air testing while their BW agent effectiveness was verified in animal tests. Substantial quantities of BW agents were filled into weapon systems (e.g., nearly 10,000 liters of botulinum toxin and 6,500 liters of *Bacillus anthracis*) and then deployed, with pre-authorization for their use, in January 1991 at four locations where they remained throughout the war. Iraq has declared that after the end of the war, their BW weapons and agent stockpiles were destroyed and records of their programs were concealed.

APPENDIX B



ASSISTANT TO THE SECRETARY OF DEFENSE
3050 DEFENSE PENTAGON
WASHINGTON, DC 20301-3050

DEP SEC DEF
HAD SEEN
APPR'd JMD
MAY 19 1994



1994 MAY 17 AM

MAY 1994 OF THE
SECRETARY OF DEFENSE

EXECUTIVE SUMMARY

MEMORANDUM FOR DEPUTY SECRETARY OF DEFENSE

THROUGH: UNDER SECRETARY OF DEFENSE (ACQUISITION & TECHNOLOGY)

FROM: ASSISTANT TO THE SECRETARY OF DEFENSE (ATOMIC ENERGY)
Prepared by Lt Col Jeff Thomas, OATSD(AE), X51097

SUBJECT: Proposed Charter for the Joint Program Office (JPO) for
the DoD Biological Defense Program

PURPOSE: ACTION - SIGNATURE on the proposed charter

DISCUSSION: The proposed charter (Tab A) defines the roles and
organizational structure for the Joint Program
Office for the DoD Biological Defense Program.
The proposed charter and organizational chart has
been staffed and approved conceptually by the
three services. Services' comments (Tab B) appear
to support the charter, however, the Navy supports
the charter with a reduced number of Navy billets
in the organizational structure.

General Wooten as the Program Manager, has
indicated the willingness to accept a reduced
number of Navy billets.

RECOMMENDATION: Deputy Secretary of Defense sign the proposed
charter at Tab A.

DEPSECDEF DECISION:

☒ Approved John M. Deutch
☐ Disapproved



REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
OFFICE OF THE ASSISTANT SECRETARY
RESEARCH DEVELOPMENT AND ACQUISITION
103 ARMY PENTAGON
WASHINGTON DC 20310-0100



SFAE-BD (70-1k)

April 18, 1994

MEMORANDUM THRU MILITARY DEPUTY TO THE ASSISTANT SECRETARY
OF THE ARMY (RESEARCH, DEVELOPMENT AND
ACQUISITION)

ASSISTANT TO THE SECRETARY OF DEFENSE (ATOMIC
ENERGY) *BKhop 4 May 94*

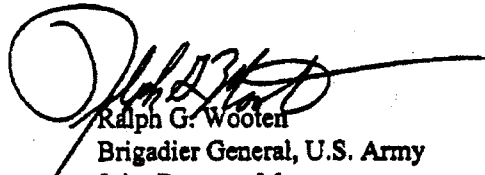
FOR UNDERSECRETARY OF DEFENSE (ACQUISITION AND TECHNOLOGY)

SUBJECT: Charter Joint Program Office for Biological Defense (JPO-BD).

The purpose of this memorandum is to forward the charter for the Joint Program Office for Biological Defense to the Under Secretary of Defense (Acquisition and Technology) (USD(A&T)) for approval and signature.

The JPO-BD has been working to move the office forward since the Defense Acquisition Board of 3 February 1994. The organizational chart (wiring diagram) has been staffed and approved conceptually by the three services. This charter brings focus to the broad guidelines issued in the June 28, 1993 Acquisition Decision Memorandum.

Recommend the USD(A&T) approve and sign the charter and the transmittal memorandum enclosed with the package.


Ralph G. Wooten
Brigadier General, U.S. Army
Joint Program Manager
for Biological Defense

Enclosures

1. ASN(RD&A) (Memo 11 Apr 94), Subj: JPO-BD Staffing Plan
2. DAF (Memo 17 Mar 94), Subj: JPO-BD Staffing Plan

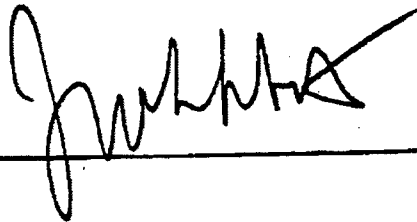
TAB A

JOINT PROGRAM OFFICE (JPO)
BIOLOGICAL DEFENSE PROGRAM

CHARTER

1. The Secretary of Defense (DoD) views Biological Defense (BD) initiatives as vital to the development and execution of our National Strategy.
2. In that context and to ensure comprehensive organizational focus, I have established a Joint Program Office (JPO) under the cognizance of a Joint Program Manager (JPM). The JPM shall report to the Undersecretary of Defense (Acquisition and Technology) (USD(A&T)) (Defense Acquisition Executive [DAE]), through the Army Acquisition Executive (AAE), with oversight by the Assistant to the Secretary of Defense (Atomic Energy) (ATSD(AE)).
3. The JPM shall serve as the principle advocate and single point of contact for all BD detection and vaccine acquisition efforts within the scope of this Charter. The JPM shall provide intensive centralized management of assigned medical and non-medical programs to expedite materiel solutions for validated BD deficiencies. The JPM shall also monitor BD technology based activities to promote and facilitate transfer and acceleration of emerging technologies to user applications across the military services.
4. The JPO Mission and Functions is at Enclosure 1 and shall serve as the MOA with all participating Services.
5. This Charter will be reviewed annually and updated or changed as required.

APPROVED: _____

A handwritten signature in black ink, appearing to be 'J. H. H.', is written over a horizontal line.

Enclosures

Enclosure 1

JOINT PROGRAM OFFICE (JPO)
BIOLOGICAL DEFENSE PROGRAM

Mission and Functions

1. **Purpose.** This document formally defines the "Mission and Functions" of the JPO to provide centralized management and joint program integration for the Department of Defense (DoD) Biological Defense Program. It will also serve as a Memorandum of Agreement (MOA) with the individual services.

2. **Background.**

a. On June 28, 1993, the USD(A&T), in his Acquisition Decision Memorandum (ADM), established a Joint Program Office (JPO) with the Army as the lead Service, while maintaining DAB level oversight of the program through periodic reviews (approximately every six months).

b. The ADM stated:

- (1) the biological defense effort is not a Major Defense Acquisition Program (MDAP) as statutorily defined by 10 U.S.C. 2430, and therefore it will not be managed as an MDAP.
- (2) the ATSD(AE) shall work with the Army to ensure that a blue ribbon technology advisory group reviews both the JPO and related technology base activities.
- (3) DoD 6.3B, 6.4, and procurement efforts in biological agent detection and biological agent vaccines shall be transferred to a single, fenced, Army Biological Defense program element (PE) managed by the JPO.

3. **Mission.** The JPO will provide centralized program management of assigned biological defense programs in accordance with applicable statutes, DoD Directive 5000 series and lead service policy.

4. **Authority.** The Joint Program Manager (JPM) acts with the authority of the DAE through the AAE with oversight by the (ATSD(AE)).

5. **Functions.**

a. The JPO will report to the DAB every six months on the progress of the Biological Defense Program, unless otherwise directed or required.

b. The JPM, with the advice and consent of the AAE, is the Services' Milestone Decision Authority (MDA) for all assigned ACAT III/IV programs.

c. The JPO will manage assigned biological defense programs (Tab A) and monitor related programs and technology base activities (Tab B). The JPM is responsible for approving program and acquisition strategy, as the MDA for assigned ACAT III/IV programs, and for preparing documentation tailored for the DAB level reviews. The JPO shall manage all assigned 6.3B, 6.4, (now 6.4, 6.5 in accordance with budgetary definitions) and procurement efforts for the Biological Defense Program. The JPO will be responsible for the procurement and stockpiling of licensed vaccines and will interface with the Army's Health Facilities Planning Agency (HFPA) for programmatic and executive level management of the vaccine production facility (VPF) construction project. The HFPA will have on-site management responsibility for the VPF construction project.

d. The JPM, as MDA, with the advice and consent of the AAE, is the Services' approval authority for the Acquisition Program Baselines (APB) of all assigned ACAT III/IV programs.

e. The JPO will allocate funding resources to assigned biological defense programs to accomplish the approved APB(s).

f. The JPO will centrally manage joint funding through a single PE, and provide Program Objective Memorandum (POM) input for assigned programs and prepare required budget documents. The JPO will prepare the required Planning Programming Budgeting System (PPBS) documentation based on Service requirements through the Army POM process.

g. The JPO may propose additional Science and Technology (S&T) Base funding through Service committees to the Service Acquisition Executives. The JPO will conduct a minimum of one execution/budget S&T review annually of the Services' S&T programs to ensure the Services recognize technology needs and desired time frames for transition, and to support funding priorities.

h. The JPO will formulate, as required, a Joint Mission Area Analysis and a Joint Mission Need Analysis, resulting in concept studies, evaluations, and recommendations for DoD Biological Defense. These documents will be submitted to the Services and the joint committees listed in paragraph 5k, to aid in the development of requirements documents.

i. The JPO will formulate and issue specific Memorandums of Agreements (MOAs) with organizations which have programs, technologies, functions, processes, or applications related to, or in support of, biological defense. The JPM is responsible for the biological portion of joint development efforts. Operational support is to be provided by the Army Office of the Surgeon General (OTSG). Technical matrix support is to be provided by the executing Service organizations.

j. The JPO will provide a representative to the Joint Service Review Group (JSRG), Joint Service Coordinating Committee (JSCC) for Chemical Defense Equipment, the Joint Panel for Chemical and Biological Defense (JP-CBD), the Joint Directors of Laboratories (JDL) Technical Panel for Chemical and Biological Defense (TP-CBD) and the Joint Technology Coordinating Group-4 (JTCG-4), which is a subcommittee of the Armed Services Biomedical Research and

Evaluation Management (ASBREM), to ensure involvement in existing Services' biological defense acquisition programs. The JPO will coordinate in the preparation of U.S. positions associated with assigned biological defense programs for international meetings/working groups involving assigned systems.

k. The JPO will establish advisory groups as required, within statutory guidelines, to include a Joint General/Flag Officer Steering Committee (JGOSC) through the authority of the Army Acquisition Executive. The JGOSC will provide operational and programmatic counsel and act as an advocate for Service issues.

l. Upon successful fielding of assigned biological defense systems, the JPO will transition management to the appropriate Materiel Command responsible for system sustainment.

6 Organization. See Tab C.

TAB B

- o Participates in the Development of Acquisition Program Baselines
- o Coordinates Program Exit Criteria
- o Ensures Quality Input to the PPBS and POM

Interface:

- o Reports tThrough the Deputy Joint Program Manager to the Joint Program Manager
- o Coordinates with the Intelligence Community
- o Coordinates with DoD and Service Acquisition Principles and their Staff through the JPO-BD Liaison Officer

JOINT PROGRAM MANAGER'S LIAISON OFFICER:

Scope:

- o Serves as the Single Conduit for JPO/PEO Type Actions in the Pentagon to Assure Real-Time Interface with the Services and Secretariat Staffs
- o Provides Services' Headquarters Staff Coordination for JPO-BD
- o Coordinate with the DoD Staff
- o Coordinate PAO and Congressional Affairs Actions with the JPO-BD
- o Coordinate with the Joint Staff (JCS)

Interface:

- o Reports to the Deputy Joint Program Manager
- o Coordinates with the Assistant Joint Program Managers
- o Represents the Joint Program Manager at DoD/Service Level Meetings as Required

- o **Division Chief Serves as Principal Advisor to the Joint Program Manager/ Deputy Program Manager on Technical Issues**
- o **Translates Policy and Guidance into Specific Technical Goals and Objectives**
- o **Reviews Program Test Plans and Ensures Funding Sufficiency for the Execution of the JPO Test and Evaluation Program**
- o **Reviews Integrated Logistics Support Package Documentation for Assigned Programs and Provides Guidance and Control for Bio Defense Materiel Fielding.**

Interface:

- o **Reports to the Deputy Joint Program Manager**
- o **Coordinates with Joint Directors of Laboratories, International Task Forces, Tech Base Blue Ribbon Panel and Joint Committees like the JSRG, TP-CBD and JSCC**
- o **Mentors the Assistant Joint Program Managers**

SYSTEMS BRANCH:

Scope:

- oo **Reviews and Assesses Technical and Acquisition Documentation and Provides Guidance to Assigned Biological Defense Programs.**
- oo **Analyzes Biological Detection Program Baselines Against Program Execution to Ensure Schedule and Performance are Tracking with Estimates**
- oo **Ensures Development of Logistics Documentation and Assesses Suitability for Program Fielding**
- oo **Ensures Implementation of JCALS in Biological Defense Initiatives**
- oo **Ensures Development of Multi/Joint Service TEMP(s)**
- oo **Assesses Testability of Combat Developer Requirements**

- oo Assists in Coordinating Requirements for FDA Licensing of Production Vaccines. Reviews and Provides Guidance on Program Efforts for Investigational New Drugs (IND) Transitioned to the JPO-BD as well as Vaccine Production for the Biological Defense Program
- oo Prepares Functional Area Documentation for DAB Reviews

Interface:

- oo Provides Matrix Support to Assistant Joint Program Managers
- oo Reports to the Program Division Chief
- oo Participates with the JSCC, JTCG-4, TP-CBD and JP-CBD
- oo Coordinates with DOTE/DDRE
- oo Chairs/Participates on Multi-Service and Cooperative TIWGs
- oo Participates with HFPA and COE

OPERATION SUPPORT BRANCH:

Scope:

- oo Branch Chief Serves as JPO Executive Officer for JPM/DJPM
- oo Reviews Bio Defense Strategy and Ensures Crosswalk with Joint Mission Area Analysis
- oo Reviews and Analyzes Requirements
- oo Tracks Policy, Doctrine, Threats as They Relate to Biological Defense Detection and Vaccines
- oo Ensures Standardization of Bio Simulation Standards and Models
- oo Responsible for Coordination of DAB and IPR Documentation
- oo Develops Memorandums of Agreement

- oo Provides JPO-BD OPSEC, COMSEC, Program Classification Guidance and ADP Security
- oo Controls the Local Area Network and IMO Capability
- oo Ensures and Administers Quality Control of Internal and External Staffing
- oo Provides Administrative Support to the JPO

Interface:

- oo Provides Matrix Support to the Assistant Joint Program Mangers
- oo Reports to the Program Division Chief
- oo Participates on Joint Service Review Groups
- oo Coordinates with Combat Developers and Battle Labs
- oo Serves as the POC for the Support Agency Agreement
- oo Interfaces with OSD(P), OSD(AE) and the Intelligence Community

ASSISTANT JOINT PROGRAM MANAGERS:

Scope:

- o Ensures Development of Service Bio Defense Acquisition Strategies
- o Ensures Generation of Programmatic Documents
- o Participates in Design Reviews
- o Chair Program Reviews as Required on Behalf of the JPM
- o Manages JPO Assigned 6.3B, 6.4 and Production Medical and Non-Medical Programs
- o Reviews Intelligence Assessment of the Biological Threat

TAB C

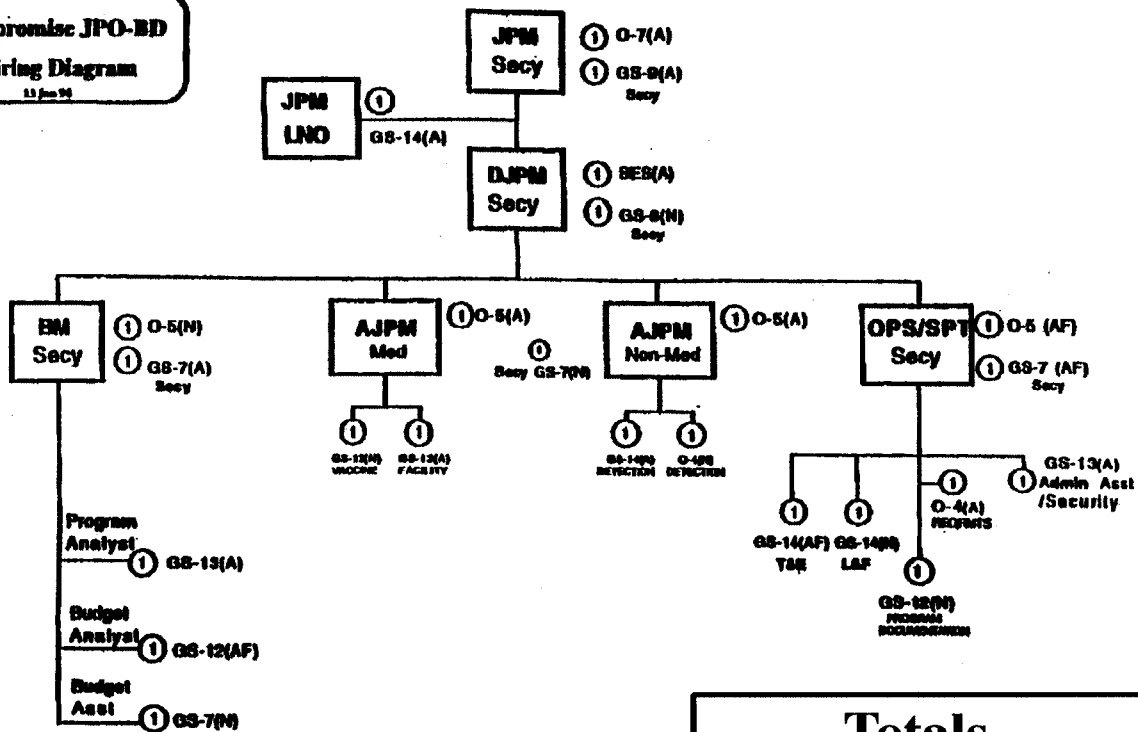
Assigned Programs

Vaccine Production & Procurement	Army
Investigational New Drug Vaccine Procurement	Army
Bio Detection Kit	Army
Bio Integrated Detection System	Army
Standoff Capability	Army
Interim Bio Agent Detection System	Navy
Bio Agent Detection System	Navy

Monitored Programs

Med Bio Defense	Army
Bio & Chem Detector	Army
Chem & Bio Mass Spectrometer	Army
Nuclear, Bio & Chem Warning System	Marine Corps
Individual Nuclear, Bio & Chem Detector & Monitor	Marine Corps
Nuclear, Bio & Chem Recon System	Marine Corps
Morning Song	Air Force
BW Pathogen/Toxin Detector	Air Force

Compromise JPO-BD
Wiring Diagram
 11 Jan 94



Totals
 Civ - 17(8-A, 6-N, 3AF)
 Mil - 7(4-A, 2-N, 1-AF)

APPENDIX C

DISEASE CHARACTERISTICS OF POTENTIAL BIOLOGICAL AGENTS					
BACTERIA					
Microorganism/ Toxin	Method of Dissemination	Incubation Period	Illness Duration	Signs and Symptoms	Medical Treatment
<i>Bacillus anthracis</i> (Anthrax)	Aerosol	2-7 days	3-5 days	Biphasic illness: onset-nonspecific, fever, cough; 48-72 hours later: acute respiratory distress, prostration	Licensed vaccine. Ciprofloxacin on exposure or at the earliest signs of disease; begin immunization concurrently
<i>Brucella species</i> (Brucellosis)	Terrorism Aerosol	5-60 days	Weeks-months	Wax and wane fever, headache, muscle and joint pain, influenza-like symptoms, debilitation	600-900mg Rifampin + 200mg Doxycycline daily x 6 weeks
<i>Vibrio cholera</i> (Cholera)	Terrorism Aerosol	12 hours to 6 days	6 hours-5 days	Abrupt onset of voluminous watery diarrhea, vomiting, muscle cramps, severe dehydration, prostration	Oral rehydration + tetracycline 1-2gms/day x 5 days
<i>Burkholderia mallei</i> (Glanders)	Aerosol	Days to weeks	10-14 days (Soviet strain 3-5 days)	Acute: nasopharyngeal ulcers, fever, septicemia, cough, prostration chronic: cold-like symptoms, lymphadenopathy, multiple abscesses, incapacitation	Sulfamethoxazole-Trimethoprim (800mg + 160mg) BID x 14 days; may need to extend treatment
<i>Yersinia pestis</i> (Plague)	Aerosol	1-3 days	1-6 days	Fever, shortness of breath, cough pneumonia, prostration	Early after onset of symptoms, tetracycline 2gm loading dose + 500mg QID ^a until patient free of fever for at least 3 days
<i>Francisella tularensis</i> (Tularemia)	Aerosol	1-10 days	2-10 days	Fever, cough, pneumonia, headache, incapacitation	Tetracycline 500mg QID ^a 14 days or Gentamicin 200mg TID ^b x 3-5 days
<i>Rickettsia prowazekii</i> (Typhus)	Insect vectors Aerosol	5-14 days	2-10 days	Acute onset, chills, headache, fever, general pain and macular ^c rash (spares face, palms, & soles) on 5-6th day of illness, prostration	Tetracycline, 2-3gms loading dose + 500mg QID until fever subsides
<i>Coxiella burnetii</i> (Q Fever)	Aerosol	14-26 days	10-14 days	Sudden onset, chills, retro-ocular ^d headache, malaise, sweating, cough, minimal physical findings, incapacitation	Tetracycline 500mg QID until patient is free of fever

^a QID - 4x daily

^b TID - 3x daily

^c macular - a flat red spot

^d retro-ocular - behind the eye

DISEASE CHARACTERISTICS OF POTENTIAL BIOLOGICAL AGENTS					
BACTERIA					
Microorganism/ Toxin	Method of Dissemination	Incubation Period	Illness Duration	Signs and Symptoms	Medical Treatment
Orientia tsutsugamushi (Scrub Typhus)	Insect vectors Aerosol	2-5 days	14-21 days	Primary skin ulcer (eschar) followed by onset of acute fever, profuse sweating, adenopathy, incapacitation; late in 1st week of fever has dull red maculopapular ^e rash on trunk spreading to extremities & disappearing in a few days. Pneumonia is common.	Tetracycline 2-3gm loading dose & then 500mg QID until fever subsides, give second loading dose after 6 day interval.

^e maculopapular - a flat red spot with a raised center

DISEASE CHARACTERISTICS OF POTENTIAL BIOLOGICAL AGENTS					
VIRUSES					
Microorganism/ Toxin	Method of Dissemination	Incubation Period	Illness Duration	Signs and Symptoms	Medical Treatment
Eastern equine encephalitis virus (EEE)	Insect vectors Aerosol	5-15 days	7-21 days	Acute onset, fever, stiff neck, disorientation, headache, stupor, coma, incapacitation	None - symptomatic
Ebola virus (Ebola fever)	Aerosol	2-21 days	7-16 days	Sudden onset, malaise, fever, muscle pain, headache, pharyngitis ^a , followed by vomiting & diarrhea, maculopapular ^c rash, limited hepatic & renal involvement and generalized hemorrhage into tissues, prostration	None - symptomatic
Marburg virus (Marburg)	Aerosol	3-9 days	7-21 days ^b		None - symptomatic
Variola (Smallpox)	Aerosol	10-12 days	21-28	Sudden onset of fever, malaise, headache, severe backache & prostration. After 2-4 days fever falls & rash appears in stages: macules ^d , papules ^e , pustules ^f & scabs which fall off at end of 4th week of illness	Licensed vaccine. Symptomatic; Vaccinia Immune Globulin (VIG)
Venezuelan equine encephalitis virus (VEE)	Insect vectors Aerosol	1-6 days	3-5 days	Abrupt onset of severe headache, chills, fever, muscle pain, retro-ocular ^g pain, nausea and vomiting, incapacitation	Symptomatic
Western equine encephalitis virus (WEE)	Aerosol	5-15 days	Days-weeks	Acute onset, high fever, headache, stiff neck, stupor, disorientation, coma, spasticity, tremors, convulsions, incapacitation	Symptomatic

^a pharyngitis - inflammation of the throat

^b Virus recovered from semen on 61st day after onset of illness

^c maculopapular - a flat red spot with a raised center

^d macule - a flat red spot

^e papule - a small elevation of the skin

^f pustule - elevation of the skin containing pus

^g retro-ocular - behind the eye

DISEASE CHARACTERISTICS OF POTENTIAL BIOLOGICAL AGENTS					
TOXINS					
Microorganism/ Toxin	Method of Dissemination	Incubation Period	Illness Duration	Signs and Symptoms	Medical Treatment
<i>Clostridium botulinum</i> (Botulism)	Terrorism Aerosol	12-48 hours	Days to months	Blurred double vision, dry mouth, difficulty swallowing, descending symmetrical flaccid paralysis, shortness of breath. Initially vomiting and diarrhea or constipation, prostration	Equine immune globulin heptavalent F(AB) ₂ (IND)
<i>Clostridium perfringens</i> (Gas Gangrene)	Terrorism Aerosol	Minutes to hours	6-24 hours	Acute pain, fever, solid tissue necrosis, gas bubbles in affected tissue, incapacitation	Radical debridement ^a ; massive doses of penicillin
Tricothecene mycotoxicosis (Yellow Rain)	Aerosol Terrorism	2-4 hours	Days to months	Burning skin & mucous membranes, weakness, light-headedness, shortness of breath, hemorrhage from mucous membranes & G.I. tract, incapacitation	None - symptomatic
Marine soft coral (Palytoxin)	Terrorism	Minutes	Minutes to hours	Nausea, vomiting, malaise, generalized bleeding into tissues, prostration	None - symptomatic
Castor bean (Ricin)	Aerosol Terrorism	Hours to days	Days	High fever, pain, cough, shortness of breath, prostration	None - symptomatic
<i>Staphylococcus aureus</i> (Staphylococcal enterotoxin)	Aerosol Terrorism	1-6 hours	1-5 days	Fever, cough, nausea, pneumonia, incapacitation	None - symptomatic
Dinoflagellate (Saxitoxin)	Aerosol Terrorism	Minutes	Minutes to days	Acute onset of numbness of face and extremities, motor difficulty in getting up/standing up, difficulty in speaking, shortness of breath, dizziness, transient blindness, respiratory failure, prostration	None - symptomatic
Puffer fish (Tetrodotoxin)	Aerosol Terrorism	Minutes to hours	Minutes to days	In addition to characteristics manifested by saxitoxin, vomiting and hypertension are common, prostration	None - symptomatic

^a debridement - the surgical removal of lacerated, devitalized, or contaminated tissue

APPENDIX D

TABLE 1 - SUMMARY OF CLINICALLY SIGNIFICANT VACCINE/DRUG INTERACTIONS*

<i>Vaccine</i>	<i>Drug</i>	<i>Mode of Exposure</i>	<i>Result</i>	<i>Reference</i>
Live vaccines (as a class)	Immunosuppressants (as a class**)	Live vaccine recipients on immunosuppressants	Partial or complete impairment of antibody response; adverse drug effects increased; impaired T-cell function	25***
Varicella Vaccine	Acyclovir	Simultaneous exposure	Impaired active immunity in many recipients	26
BCG Vaccine	Isoniazid (INH)		Impaired active immunity in most recipients	27
BCG Vaccine	Theophylline		Increase toxicity of theophylline due to decreased elimination	28
HDCV****	Chloroquine	HDCV recipients on long-term therapy with chloroquine	Depressed antibody response when HDCV is administered by intradermal route	29
Influenza Vaccine	Carbamazepine	Influenza vaccine recipients on carbamazepine	Increased toxicity due to decreased elimination	30
Influenza Vaccine	Phenobarbital	Influenza vaccine recipients on Phenobarbital	Increased toxicity due to decreased elimination	30
Influenza Vaccine	Phenytoin	Influenza vaccine recipients on phenytoin	Increased toxicity due to decreased elimination	30

* A partial list of vaccine-drug interactions in the published literature (Medline: 1980-1996) with responses identified by the author as clinically significant.

** This class includes alkylating agents, antimetabolites, antithymocyte Abs, corticosteroids, cyclosporine, radioisotopes, etc.

*** IPAC = Immunization Practices Advisory Committee;

**** HDCV = Human diploid-cell rabies vaccine

APPENDIX E

**FOOD AND DRUG ADMINISTRATION (FDA) INSPECTION
OF THE
MICHIGAN BIOLOGIC PRODUCTS INSTITUTE (MBPI)**

A. Background

During the preparation of this JVAP dPEA, FDA inspectors conducted an inspection of MBPI. As FDA reported to MBPI in a letter dated March 11, 1997, this inspection found that some MBPI procedures and record-keeping practices were not in compliance with FDA regulations. Failure to correct deviations and comply with FDA regulations may result in FDA revocation of MBPI's establishment license. Because this JVAP dPEA relies, in part, on the site-specific EA conducted in 1993 at MBPI, it is important to discuss this FDA inspection in this document. It should be noted that the State of Michigan is transferring MBPI out of government. Once this is done, MBPI will no longer be part of Michigan State Government. Privatization of MBPI is viewed as a positive and necessary step in MBPI attaining and remaining in full compliance with FDA regulations. Private management should significantly improve the institute's flexibility to appropriately and effectively address administrative non-compliance issues. The current lack of such flexibility under state personnel and management rules and procedures has proven to be a major impediment to ensuring continued compliance with FDA-mandated standards.

B. FDA Letter of March 11, 1997 to MBPI

1. Nature of the letter. The Inspectional Observations made by the FDA during the November 1996 inspection were associated primarily with the lack of certain required written procedures, and with failure to follow written procedures for the manufacturing process for blood derivatives products and the rabies vaccine. Noncompliance instances cited by the FDA can be grouped in the following areas:
 - (a) Quality Control. The quality control unit failed to approve or reject components, procedures, or specifications of the manufacturing process through approval and release procedures.
 - (b) Process SOPs. The FDA noted a failure to establish and/or follow written procedures for production and process controls.
 - (c) Control SOPs. There was a failure to establish and follow mandatory process control procedures to validate performance of manufacturing processes that possibly caused variability of in-process materials and the products.
 - (d) Test SOPs. There was a failure to establish and/or follow test procedures for stability programs for the immune globulin and rabies vaccine, to establish separate or defined areas that would reduce potential contamination or mix-ups; and to maintain or sanitize equipment at appropriate intervals that would reduce malfunction or contamination.
 - (e) Calibration. Calibration of equipment was not routinely performed according to written procedures.

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Final Programmatic Environmental Assessment

- (f) Management. Management had not exercised control in all matters relating to compliance with Federal regulations or to assure that personnel were adequately trained and supervised.
 - (g) Housekeeping and Maintenance. Some areas were in a poor state of repair.
2. Previous FDA visits. The March 11, 1997, FDA letter pointed out that prior to the inspection in November 1996, FDA inspected MBPI in May of 1993, May-June of 1994, and April-May of 1995 where deviations from current Good Manufacturing Practices (cGMP) were noted. Some of these were repeat deviations, and a Warning Letter was issued in August 1995.
3. FDA reaction to previous MBPI responses. Following each inspection and the Warning Letter, MBPI corrected some of the deviations and proposed corrective action for others. In the March 11, 1997, letter, the FDA was concerned that corrective actions promised in the past were not yet completed and that the follow-up inspection showed that long-term corrective action had not been taken. FDA stated that it had no assurance that corrective actions proposed in MBPI's January 1997 response would be properly implemented. FDA served notice in its March 11, 1997, letter of specific requirements to demonstrate or achieve compliance with Federal regulations. If these requirements are not met, FDA will institute proceedings to revoke the MBPI establishment license to manufacture its biologic products. FDA required a letter from MBPI within 10 days to commit to correcting the deficiencies. Further, the FDA required that within 30 days of its letter, MBPI prepare a comprehensive report and a detailed plan to bring the facility into compliance and to provide proposed timelines for the completion of corrections for each deficiency.

C. Distribution of MBPI Products

Despite the March 11, 1997, letter, FDA continues to release lots of MBPI products based on review of the MBPI lot release test results, and on the basis of any tests that FDA chooses to perform on samples of the products submitted to FDA by MBPI. In the case of the anthrax vaccine, these tests demonstrate that the final product for distribution meets requirements for product sterility, purity, safety, and potency as defined in 21 CFR. The FDA inspection of MBPI operations did not identify any significant adverse environmental impacts resulting from the cited deficiencies.

D. DoD Assessment and Actions

Following the August 1995 Warning Letter, DoD provided MBPI with on-site assessment and assistance. Corrective actions and the prioritization of these corrective actions were recommended to MBPI by DoD to facilitate compliance of the total facility. MBPI notified DoD of the results of FDA inspections and the March 11, 1997, letter stating FDA's requirement for a concrete commitment to corrective actions. DoD assistance was expanded in response to the March 11, 1997, FDA letter. DoD and FDA have discussed this project and the

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FDA is aware of DoD participation in resolving the issues and in responding to the March 11, 1997, FDA letter. DoD's continued, increased involvement and assistance in institute operations are expected to improve the institute's future compliance.

E. MBPI Responses and Actions

1. MBPI 10-day response. MBPI submitted the 10-day response on time and committed to correcting all deficiencies.
2. MBPI 30-day response. MBPI submitted the 30-day response on time, providing substantial detail on a plan to bring the facility into compliance with regulations. One key approach is the move from a State-controlled facility to a private-sector company. As a State-controlled facility, the director of the facility has little or no control over State maintenance procedures and priorities, or over personnel under the civil service system. In phases, State control is being transferred to MBPI, and MBPI is being structured similar to a commercial pharmaceutical organization with new personnel positions to ensure compliance. State funding will continue through 1997, and commercial partners are participating in bringing the facility into regulatory compliance. The partners include two commercial companies involved in plasma fractionation and childhood vaccines, and the DoD with an investment in anthrax vaccine. The detailed plan submitted by MBPI describes a transition team to facilitate the change to the private sector as well as resolve compliance problems. It also describes the progress in facilities upgrades, management changes, and training designed to respond to FDA Inspectional Observations, and commits to timelines to complete the changes and corrective measures required for compliance.

F. Environmental Consequences of FDA-Cited Deviations at MBPI

1. MBPI site-specific environmental impacts. This JVAP dPEA references two NEPA analyses of actions at MBPI: the 1993 site-specific MDPH (now MBPI) EA, and the ongoing MBPI EA to examine expanded procurement of licensed anthrax vaccine, which was initiated in March 1997. This JVAP dPEA must take into account the findings of the FDA inspection at MBPI and their potential impact upon the dPEA conclusions.
2. Assessment of FDA-cited deviations at MBPI. This appendix assesses the likely environmental impacts resulting from the FDA-cited deficiencies at MBPI. Table E-1 summarizes the assessment of potential relevance of the FDA-cited deviations to each of the environmental resource categories discussed in the dPEA. In most cases the deviations are not relevant. In the cases where there is some potential relevance, it is of a minor nature. Table E-2 summarizes the analyses of the potential environmental impacts associated with those FDA-cited deviations found to have potential relevance to a resource category.
3. Conclusions. While the MBPI management failures cited by the FDA may increase the likelihood of a significant adverse environmental consequence as shown by the analyses in

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Table E-2, the probability of such an adverse consequence remains very low. FDA did not identify any adverse environmental impacts resulting from these deviations. The FDA-cited deficiencies, under the circumstances discussed herein, are not likely to have a significant impact on the environment. As such, the conclusions reached by this dPEA remain the same.

G. Conclusion and Implications for this JVAP dPEA

1. Programmatic environmental impact. Throughout this document, it can be seen that the potential for significant adverse environmental impacts is minimized by effective application and enforcement of both Federal, State, and local laws and regulations and of pharmaceutical industry practices and procedures. Analyses of the proposed vaccine acquisition activities conclude that the JVAP may be performed with no significant impacts. The FDA inspection of MBPI and the resulting requirements for corrective actions by MBPI as a necessary condition for continuation of its FDA license demonstrate that the enforcement system is effective. These events reinforce the conclusion that the JVAP may be conducted with no significant impacts.
2. Impact of deviations. No significant impacts have resulted from the FDA-cited deficiencies. MBPI can continue licensed production and testing, obtain lot release, and distribute product. Neither the site-specific MBPI EA conducted in 1993 nor preliminary findings of an ongoing site-specific MBPI EA started on March 11, 1997, have identified significant impacts.

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Final Programmatic Environmental Assessment

Table E-1. Assessment of Relevance of FDA-Cited Deviations to Environmental Attributes

Area of FDA-Cited Deviation and Relevance to Environmental Attributes (<i>N</i> = No relevance)							
Environmental Attributes	Quality Control	Process SOPs	Control SOPs	Test SOPs	Calibration	Management	House-keeping
4.4.1 Plant & Animal Ecology	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>
4.4.2 Land Use	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>
4.4.3 Environmental Justice	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>
4.4.4 Surface Water	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>
4.4.5 Groundwater	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>
4.4.6 Geology	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>
4.4.7 Historical & Cultural Resources	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>
4.4.8 Agriculture	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>
4.4.9 Climate	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>
4.4.10 Energy Resources	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	Minor relevance	<i>N</i>	<i>N</i>
4.4.11 Noise	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>
4.4.12 Odors	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>
4.4.13 Socioeconomic Environment	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>
4.4.14 Transportation	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>
4.4.15 Air Quality	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>
4.4.16 Public Opinion	Minor relevance	Minor relevance	Minor relevance	Minor relevance	Minor relevance	Minor relevance	Minor relevance
4.4.17 Program Benefits	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>
4.4.18 Human Health & Safety*							
4.4.18.1 Public Health & Safety	<i>N</i>	<i>N</i>	Minor relevance	<i>N</i>	<i>N</i>	Minor relevance	Minor relevance
4.4.18.2 Worker Health & Safety	<i>N</i>	<i>N</i>	Minor relevance	<i>N</i>	<i>N</i>	Minor relevance	Minor relevance
4.4.18.3 Health & Safety of Vaccine Recipients	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>
4.4.18.4 Accidents & Incidents	<i>N</i>	Minor relevance	Minor relevance	<i>N</i>	<i>N</i>	Minor relevance	Minor relevance
4.4.19 Consequences of JVAP Actions Abroad	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>	<i>N</i>
Cumulative Impacts	Minor relevance	Minor relevance	Minor relevance	Minor relevance	Minor relevance	Minor relevance	Minor relevance

* Human Health & Safety includes the subcategories on public, worker, and recipient health and safety and is not evaluated independently of these subcategories.

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Table E-2. Analysis of the Potential Environmental Impacts of FDA-Cited Deviations

Environmental Attributes	FDA-Cited Deviation and Potential Environmental Impacts
4.4.10 Energy Resources	Calibration: Insignificant negative impact. Failure to calibrate recording devices resulted in minor increased energy consumption in that a freezer was maintained at lower temperatures than required. Housekeeping: Negligible. Although not cited as a consequence, failure to clean and maintain equipment may result in less than optimal energy consumption.
4.4.16 Public Opinion	FDA-cited deviation from 21 CFR standards and regulations result in insignificant negative impacts. It is reasonable that public concerns about MBPI products would increase as a result of the publicity surrounding this inspection and the March 11 letter. The conclusion that these concerns are insignificant is reinforced by the continued acceptance and use of MBPI products (e.g., CDC requested use of MBPI immunoglobulin in response to Hepatitis A outbreak in Mar-Apr 97).
4.4.18 Human Health & Safety*	
4.4.18.1 Public Health & Safety	Deviation from 21 CFR standards and regulations may result in insignificant negative impacts. Although risks to the public are extremely small, it is possible that ineffective control measures for segregation of work areas, personnel training and practices as well as deficient housekeeping practices could increase the likelihood of laboratory acquired infection, inadvertent transfer of live organisms from the facility, occupational diseases, and secondary infection of worker-contacted personnel. Neither the 1993 MDPH EA nor the current in-progress EA has identified any such actual impacts. The potential for such impacts is mitigated by MBPI special immunizations program to protect workers from occupationally acquired diseases and by the 30 day response measures being instituted as a result of the FDA investigation.
4.4.18.2 Worker Health & Safety	Deviation from 21 CFR standards and regulations may result in insignificant negative impacts. Risk issues are very similar to those for public health & safety (see above) and the same mitigation considerations apply.
4.4.18.3 Health & Safety of Vaccine Recipients	Deviation from 21 CFR standards and regulations diminishes the effectiveness of procedural and verification safeguards for product quality and has the potential to result in negative impacts. The FDA's reliance on satisfactory product test data as a precondition for product release and for human use prevents these potential adverse impacts from occurring. That is, products are always tested and the FDA reviews these test data prior to allowing the manufacturer to release the product. Product testing is a proven effective and direct measure to protect vaccine recipients. Additionally, adverse event reporting supports the safety of MBPI products. FDA continues to allow MBPI to produce, test, and release product. Actual impacts on vaccine recipient health and safety are negligible.
4.4.18.4 Accidents & Incidents	Deviation from 21 CFR standards and regulations may result in insignificant negative impacts. As with any occupational health and safety program, the management emphasis and requirements for development, training, and application of safe procedures and control mechanisms are important measures to minimize accidents and incidents. Despite the FDA-cited deviations in these areas, neither the MBPI safety record, the 1993 MDPH EA, nor the ongoing site-specific EA has identified this as an area of significant impact.
Cumulative Impacts	Deviation from 21 CFR standards and regulations may result in insignificant negative impacts. The presence of insignificant negative impacts for each of the FDA-cited categories in one or more environmental attributes results in insignificant negative cumulative impacts. There are no indications of significant negative cumulative impacts resulting from MBPI operations.

* Human Health & Safety includes the subcategories on public, worker, and recipient health and safety and is not evaluated independently of the subcategories.

APPENDIX F

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FINAL JVAP EA DISTRIBUTION LIST

<u>U.S. Senators</u>	DPEA NOA	DPEA	FPEA NOA	Exec. Sum.	FNSI
<u>105th Congress</u>					
U.S. Senator Spencer Abraham (R-MI) 245 Dirksen Senate Office Building Washington, DC 20510	√	√	√	√	√
U.S. Senator Mike DeWine (R-OH) 140 Russell Senate Office Building Washington, DC 20510	√	√	√	√	√
U.S. Senator John Glenn (D-OH) 503 Hart Senate Office Building Washington, DC 20510	√	√	√	√	√
U.S. Senator Carl Levin (D-MI) SR-459 Russell Senate Office Building Washington, DC 20510	√	√	√	√	√
U.S. Senator Barbara A. Mikulski (D-MD) 709 Hart Senate Office Building Washington, DC 20510	√	√	√	√	√
U.S. Senator Charles Robb (D-VA) 154 Russell Senate Office Building Washington, DC 20510	√	√	√	√	√
U.S. Senator Jay D. Rockefeller (D-WV) 109 Hart Senate Office Building Washington, DC 20510	√	√	√	√	√
U.S. Senator Rick Santorum (R-PA) 120 Russell Senate Office Building Washington, DC 20510	√	√	√	√	√
U.S. Senator Paul S. Sarbanes (D-MD) 309 Hart Senate Office Building Washington, DC 20510	√	√	√	√	√
U.S. Senator Arlen Specter (R-PA) 530 Hart Senate Office Building Washington, DC 20515	√	√	√	√	√
U.S. Senator John Warner (R-VA) 154 Russell Senate Office Building Washington, DC 20510	√	√	√	√	√

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	DPEA NOA	DPEA	FPEA NOA	Exec. Sum.	FNSI
<u>U.S. Representatives</u>					
<u>105th Congress</u>					
U.S. Representative Roscoe G. Bartlett (R-MD) 322 Cannon House Office Building Washington, DC 20515	√	√	√	√	√
U.S. Representative Tom Davis (R-VA) 224 Cannon House Office Building Washington, DC 20515	√	√	√	√	√
U.S. Representative Paul E. Kanjorski (D-PA) 2353 Rayburn House Office Building Washington, DC 20515	√	√	√	√	√
U.S. Representative Joseph M. McDade (R-PA) 2107 Rayburn House Office Building Washington, DC 20515	√	√	√	√	√
U.S. Representative Constance A. Morella (R-MD) 2228 Rayburn House Office Building Washington, DC 20515	√	√	√	√	√
U.S. Representative Deborah Pryce (R-OH) 221 Cannon House Office Building Washington, DC 20515	√	√	√	√	√
U.S. Representative Debbie Stabenow (D-MI) 1516 Longworth House Office Building Washington, DC 20515	√	√	√	√	√
<u>Federal Agencies</u>					
Nancy Roscioli Center for Biologics Evaluation & Research Food & Drug Administration 1401 Rockville Pike Rockville, MD 20852	√	√	√	√	√
Centers for Disease Control and Prevention 1600 Clifton Road, N.W. Atlanta, GA 30333	√	√	√	√	√
Environmental Review Coordinator EPA Region 2 26 Federal Plaza New York, NY 10278	√	√	√	√	√
Director, Office of Federal Activities U.S. Environmental Protection Agency Washington, DC 20420	√	√	√	√	√

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	DPEA NOA	DPEA	FPEA NOA	Exec. Sum.	FNSI
Office of Hazardous Materials Transportation U.S. Department of Transportation 400 7 th Street, S.W. Washington, DC 20590	√	√	√	√	√
Office for Protection from Research Risks (OPRR) National Institutes of Health Bethesda, MD 20892	√	√	√	√	√
Robyn Nishimi, Ph.D. Presidential Advisory Committee on Gulf War Veterans' Illness 1411 K Street, N.W. Suite 1000 Washington, DC 20005-3404	√	√	√	√	√
Secretary of Transportation U.S. Department of Transportation 400 7 th Street, S.W. Washington, DC 20590	√	√	√	√	√
U.S. Environment Protection Agency 230 South Dearborn Street Chicago, IL 60604	√	√	√	√	√
U.S. Environmental Protection Agency - Region III 841 Chestnut Street Philadelphia, PA 19107	√	√	√	√	√
<u>State Agencies</u>					
<i>Maryland</i>					
Governor Parris N. Glendening State House Annapolis, MD 21401	√	√	√	√	√
Maryland Department of the Environment 2500 Broening Highway Baltimore, MD 21224	√	√	√	√	√
Maryland Department of Natural Resources 580 N. Taylor Ave. Annapolis, MD 21401	√	√	√	√	√
Maryland Department of Transportation P.O. Box 8755 Baltimore-Washington International Airport Baltimore, MD 21240	√	√	√	√	√

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	DPEA NOA	DPEA	FPEA NOA	Exec. Sum.	FNSI
Director Maryland State Clearinghouse for Intragovernmental Assistance 301 West Preston Street Baltimore, MD 21201-2365	√	√	√	√	√
<i>Michigan</i> Executive Office of the Governor John Engler, Governor 111 South Capitol Street Lansing, MI 48933	√	√	√	√	√
Michigan Department of Natural Resources Executive Offices Steven T. Mason Building, Seventh Floor Lansing, MI 48933	√	√	√	√	√
Michigan Department of Transportation 425 West Ottawa Street Lansing, MI 48933	√	√	√	√	√
<i>Ohio</i> Governor George Voinovich 30 th Floor 77 South High Street Columbus, OH 43215	√	√	√	√	√
Ohio EPA 1800 Watermark Drive P.O. Box 1049 Columbus, OH 43216-1049	√	√	√	√	√
Ohio Department of Transportation 25 South Front Street Columbus, OH 43215	√	√	√	√	√
<i>Pennsylvania</i> Office of the Governor 225 Main Capitol Harrisburg, PA 17120	√	√	√	√	√
Pennsylvania Department of Environmental Protection 400 Market Street Rachel Carson Building Harrisburg, PA 17101-8471	√	√	√	√	√
Pennsylvania Department of Transportation 555 Walnut Street 9 th Floor, Forum Place Harrisburg, PA 17101	√	√	√	√	√

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	DPEA NOA	DPEA	FPEA NOA	Exec. Sum.	FNSI
<i>Virginia</i>					
Governor George Allen State Capitol Richmond, VA 23219	√	√	√	√	√
<u>Newspapers</u>					
Detroit Free Press Kathy O’Gorman 6200 Metro Parkway Sterling Heights, MI 48312	√		√		
Frederick News Post P.O. Box 578 200 East Patrick Street Frederick, MD 21708	√		√		
Lansing State Journal 120 East Lenawee Lansing, MI 48919	√		√		
Madison Press P.O. Box 390 London, OH 43140	√		√		
Montgomery Journal 2 Research Court Rockville, MD 20850	√		√		
Montgomery Sentinel P.O. Box 1272 Rockville, MD 20849-1272	√		√		
The Columbus Dispatch 34 South 3 rd Street Columbus, OH 43215	√		√		
The Patriot News P.O. Box 2265 Harrisburg, PA 17105	√		√		
The Washington Post 1150 15th Street NW Washington, DC 20071	√		√		
The Washington Times 3400 New York Avenue Washington, DC 20002	√		√		

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	DPEA NOA	DPEA	FPEA NOA	Exec. Sum.	FNSI
<u>Libraries</u>					
Columbus Metropolitan Library 96 South Grant Avenue Columbus, OH 43215	√	√	√	√	√
East Shore Area Library 4501 Ethel Street Harrisburg, PA 17109	√	√	√	√	√
Frederick County Public Library 110 East Patrick Street Frederick, MD 21701	√	√	√	√	√
Hurt Battelle Memorial Library 270 Lily Chapel Road West Jefferson, OH 43162-1202	√	√	√	√	√
Ingham County Library 4538 Elizabeth Road Lansing, MI 48917	√	√	√	√	√
Lansing Public Library 401 South Capital Street Lansing, MI 48933-2037	√	√	√	√	√
Library of Michigan 717 Allegan P.O. Box 30007 Lansing, MI 48909	√	√	√	√	√
Monroe County Public Library Pocono Township Branch Township Municipal Building Route 611 Tannersville, PA 18372	√	√	√	√	√
Montgomery County Public Library Rockville Branch 99 Maryland Avenue Rockville, MD 20850	√	√	√	√	√
Montgomery County Public Library Twinbrook Branch Reference Department 202 Meadow Hall Drive Rockville, MD 20851	√	√	√	√	√

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	DPEA NOA	DPEA	FPEA NOA	Exec. Sum.	FNSI
Post Library Building 501 Fort Detrick Frederick, MD 21702-5000	√	√	√	√	√
Tyson-Pimmit Library 7584 Leesburg Pike Falls Church, VA 22043	√	√	√	√	√
<u>Other Interested Parties</u>					
Albert B. Sabin Vaccine Foundation Attn: Dr. Philip K. Russell 11909 Coldstream Lane Potomac, MD 20854	√	√	√	√	√
American Legion 1608 K St., N.W. Washington, DC 20006	√	√	√	√	√
Tod Ensign Director, Citizen Soldier 175 5th Ave., Rm 2135 New York, NY 10010	√	√	√	√	√
Victor Sidel, M.D. Citizen Soldier 175 5th Ave., Rm 2135 New York, NY 10010	√	√	√	√	√
Meryl Nass, M.D. Citizen Soldier 175 5th Ave., Rm 2135 New York, NY 10010	√	√	√	√	√
Veteran of Foreign Wars Headquarters 200 Maryland Avenue, N.E. Washington, DC 20002	√	√	√	√	√
Disabled American Veterans 807 Maine Avenue, S.W. Washington, DC 20024	√	√	√	√	√
Foundation on Economic Trends 1660 L Street, N.W. Suite 216 Washington, DC 20036	√	√	√	√	√
National Gulf War Resource Center, Inc. 1224 M Street, N.W. Washington, DC 20005	√	√	√	√	√

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	DPEA NOA	DPEA	FPEA NOA	Exec. Sum.	FNSI
Dr. Sidney M. Wolfe, M.D. Public Citizen Health Research Group 1600 29th St., N.W. Washington, DC 20009	√	√	√	√	√
<u>Individual Requesters</u>					
John R. White 1837 Churchville Road Belair, MD 21015		√	√	√	√
Dr. Raymond V. Gilden Senior Vice President, Biotechnology DynCorp Fairview Center 1003 West 7th Street Frederick, MD 21701		√	√	√	√
Edward S. Syrjala P.O. Box 149 Centerville, MA 02632		√	√	√	√
Ms. Phyllis Epstein BDM, International, Inc. MS JB-4C25 1501 BDM Way McLean, VA 22102		√	√	√	√
K. Young 3940 Lander Road Jefferson, MD 21755		√	√	√	√
John Geddie 8040 Bellamah Court NE Albuquerque, NM 87110		√	√	√	√
Dr. David Robinson Room 11-9-051, Battelle 505 King Avenue Columbus, OH 43201-2693		√	√	√	√
Marguerite Duffy/EPA 401 M Street, SW, Mail Code 2252A Washington, DC 20460		√	√	√	√
David L. Stitcher Environment Safety and Health Officer Medical Research and Evaluation Facility Battelle Memorial Institute 505 King Avenue Columbus, OH 43201-2693		√	√	√	√

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	DPEA NOA	DPEA	FPEA NOA	Exec. Sum.	FNSI
Dr. Robert Myers, Director Michigan Biologic Products Institute 3500 North Martin Luther King Blvd. Lansing, MI 48906		√	√	√	√
Dr. Jack Melling, CEO The Salk Institute U.S. Route 611 Swiftwater, PA 18370		√	√	√	√
Commander, USAMRICD (COL James Little) Bldg. E3100 Aberdeen Proving Ground, MD 21010-5425		√	√	√	√
Commander, USAMRIID (COL David Franz) 1425 Porter Street Ft. Detrick, MD 21703		√	√	√	√
Commander, WRAIR (COL Ernest Takafuji) Washington, DC 20307-5100		√	√	√	√

APPENDIX G

The combined-forces training component would consist of increasing the intensity of training from a typical maximum of approximately 5,300 soldiers to approximately 10,600 soldiers during an annual training period at Camp Roberts. Four new types of equipment would be introduced at Camp Roberts as part of the proposed action: the M1 Abrams series of tanks would replace the M60 series tanks, Bradley Fighting Vehicles would replace the M113 series armored personnel carriers, the Multiple-Launch Rocket System would replace all but two of the M110 8-inch howitzers, and the AH-64 series Apache helicopters would replace the Cobra helicopters. The range modernization program component would be composed of both upgrading existing ranges and constructing new ranges.

Copies: Copies of the ROD will be mailed to individuals who participated in the public scoping process. Copies will also be sent to Federal, state, regional, and local agencies; interested organizations and agencies; and public libraries. Individuals not currently on the mailing list may obtain a copy by request.

FOR FURTHER INFORMATION CONTACT: Lieutenant Colonel William Parsonage, EIS/EIR Project Officer, Camp Roberts Army National Guard Training Site, Camp Roberts, CA 93451-5000; telephone (805) 238-8207.

Dated: June 6, 1997.

Raymond J. Fatz,

Deputy Assistant Secretary of the Army, (Environment, Safety, and Occupational Health) OASA (IL&E).

[FR Doc. 97-15276 Filed 6-10-97; 8:45 am]

BILLING CODE 3710-08-M

DEPARTMENT OF DEFENSE

Department of the Army

Draft Programmatic Environmental Assessment (PEA) for the Joint Vaccine Acquisition Program (JVAP)

AGENCY: Department of the Army, DOD.

ACTION: Notice of availability.

SUMMARY: The U.S. Department of the Army (Army) announces the availability for public review and comment of a draft PEA for the JVAP. The primary objective of the JVAP is to develop, produce, store, test, and field sufficient quantities of U.S. Food and Drug Administration (FDA) licensed vaccines to implement U.S. government policy for protecting its armed forces against biological warfare agents. Because of the current threat of biological warfare and

its continuing proliferation, there is an urgent need to protect our fighting men and women who go in harms way. The JVAP is implemented by the Department of Defense (DOD) through the Joint Program Office for Biological Defense (JPO BD) for which the Army is the lead agency. The JVAP PEA characterizes and assesses the possible and probable environmental consequences associated with the JVAP as proposed and the alternatives considered. The PEA concludes that the proposed JVAP activities and the alternatives analyzed are not likely to have significant adverse effects upon the quality of the environment.

Alternatives: a. Implement and operate the JVAP through which the Army proposes to develop, produce, store, test, and field vaccines for biological defense which are otherwise unavailable (Preferred Alternative).

b. No action (cessation of all JVAP activities now and in the future).

c. Conduct current and currently planned JVAP activities in a consolidated government facility.

d. Conduct current and currently planned JVAP activities at a consolidated contractor facility.

Comments: The JVAP Draft PEA is available for public review and comment. Mr. Bruce G. Kay is the DA clearinghouse for requests for the JVAP draft PEA and documentation from previous environmental analyses referenced in the draft PEA. Written comments for consideration in preparing the final Programmatic Environmental Assessment should be submitted to the address provided below.

DATES: The agency must receive comments on or before July 14, 1997.

ADDRESSES: Mail comments and document copy requests to: Joint Vaccine Acquisition Project Management Office, JVAP-PMO (Attn: Mr. Bruce Kay), 568 Doughten Street, Fort Detrick, Maryland 21702-5040; or phone at (301) 619-2016; or fax at (301) 619-7230; e-mail: bruce_g_kay@ftdetrick-cmail.army.mil.

Dated: June 6, 1997.

Raymond J. Fatz,

Deputy Assistant Secretary of the Army, (Environment, Safety and Occupational Health), OASA (IL&E).

[FR Doc. 97-15235 Filed 6-10-97; 8:45 am]

BILLING CODE 3710-08-M

DEPARTMENT OF DEFENSE

Defense Logistics Agency

Privacy Act of 1974; New Computer Matching Program Between the Department of Veterans Affairs and the Defense Manpower Data Center of the Department of Defense

AGENCY: Defense Manpower Data Center, Defense Logistics Agency, Department of Defense.

ACTION: Notice of a new computer matching program between the Department of Veterans Affairs (VA) and the Department of Defense (DoD) for public comment.

SUMMARY: Subsection (e)(12) of the Privacy Act of 1974, as amended, (5 U.S.C. 552a) requires agencies to publish advance notice of any proposed or revised computer matching program by the matching agency for public comment. The DoD, as the matching agency under the Privacy Act is hereby giving constructive notice in lieu of direct notice to the record subjects of a computer matching program between VA and DoD that their records are being matched by computer. The record subjects are VA delinquent debtors who may be current or former Federal employees receiving Federal salary or benefit payments and who are delinquent in their repayment of debts owed to the United States Government under programs administered by VA so as to permit VA to pursue and collect the debt by voluntary repayment or by administrative or salary offset procedures under the provisions of the Debt Collection Act of 1982.

DATES: This proposed action will become effective July 11, 1997, and the computer matching will proceed accordingly without further notice, unless comments are received which would result in a contrary determination or if the Office of Management and Budget or Congress objects thereto. Any public comment must be received before the effective date.

ADDRESSES: Any interested party may submit written comments to the Director, Defense Privacy Office, Crystal Mall 4, Room 920, 1941 Jefferson Davis Highway, Arlington, VA 22202-4502.

FOR FURTHER INFORMATION CONTACT: Mr. Aurelio Nepa, Jr. at telephone (703) 607-2943.

SUPPLEMENTARY INFORMATION: Pursuant to subsection (o) of the Privacy Act of 1974, as amended, (5 U.S.C. 552a), the DoD and VA have concluded an agreement to conduct a computer matching program between the agencies.

NOTICE OF AVAILABILITY

JOINT VACCINE ACQUISITION PROGRAM DRAFT PROGRAMMATIC ENVIRONMENTAL ASSESSMENT

The U.S. Department of the Army (DA) announces the availability for public review and comment of a draft Programmatic Environmental Assessment (PEA) of the Joint Vaccine Acquisition Program (JVAP). The primary objective of the JVAP is to develop, produce, store, test, and field sufficient quantities of U.S. Food and Drug Administration (FDA) licensed vaccines to implement U.S. government policy for protecting its armed forces against biological warfare agents. Because of the current threat of biological warfare and its continuing proliferation, there is an urgent need to protect our fighting men and women who go in harm's way. The JVAP is implemented by the Department of Defense (DoD) through the Joint Program Office for Biological Defense (JPO BD), for which the DA is the lead agency. The JVAP PEA characterizes and assesses the possible and probable environmental consequences associated with the JVAP as proposed, and the alternatives considered. The PEA concludes that the proposed JVAP activities and the alternatives analyzed are not likely to have significant adverse effects upon the quality of the environment.

The JVAP Draft PEA is available for public review and comment. Copies are available for review at the Columbus Metropolitan Library, 96 S. Grant Ave., Columbus, OH, 43215; East Shore Library, 4501 Ethel St., Harrisburg, PA, 17109; Frederick County Public Library, 110 E. Patrick St., Frederick, MD, 21701; Hurt Battelle Memorial Library, 270 Lily Chapel Rd., W. Jefferson, OH, 43162-1202; Ingham County Library, 4538 Elizabeth Rd., Lansing, MI, 48917; Lansing Public Library, 401 South Capital Street, Lansing, MI 48933-2037; Library of Michigan, 717 Allegan, P.O. Box 30007, Lansing, MI, 48909; Monroe County Public Library, Pocono Township Branch, Township Municipal Building, Rte. 611, Tannersville, PA, 18372; Montgomery County Public Library, Rockville Branch, 99 Maryland Avenue, Rockville, MD, 20850; Montgomery County Public Library, Twinbrook Branch, Reference Department, 202 Meadow Hall Drive, Rockville, MD, 20851; Post Library, Building 501, Ft. Detrick, Frederick, MD, 21702-5000; and the Tyson-Pimmit Library, 7584 Leesburg Pike, Falls Church, VA, 22043. A copy of the document may be obtained by writing to: JOINT VACCINE ACQUISITION PROJECT MANAGEMENT OFFICE, JVAP-PMO (ATTN: MR. BRUCE KAY), 568 DOUGHTEN DRIVE, SUITE 100, FORT DETRICK, MD 21702-5040. Mr. Kay is the DA clearinghouse for requests for the JVAP draft PEA and documentation from previous environmental analyses referenced in the draft PEA. Written comments for consideration in preparing the final EA should be submitted to the same address and must be received no later than July 14, 1997.

APPENDIX H

Joint Vaccine Acquisition Program
Final Programmatic Environmental Assessment

**COMMENTS RECEIVED ON THE JVAP DRAFT PROGRAMMATIC
ENVIRONMENTAL ASSESSMENT (JVAP dPEA)**

Neither Federal Regulations (40 CFR 1500-1508) nor the Department of the Army Regulation (AR 200-2; 32 CFR 651) that implement the National Environmental Policy Act (NEPA; 42 USC 4321-4370d) require providing public availability of draft environmental assessments for review and comment. However, to expand opportunities for identification and consideration of potential environmental impacts of the proposed and alternative actions, the Secretary of the Army made the JVAP dPEA available for public review and comment from June 11, 1997 through July 14, 1997. It was made available in public libraries, on the internet (<http://www.medcom.amedd.army.mil/jvap-dpea>) and distributed to individuals and organizations identified in Appendix F, JVAP PEA Distribution for Public Involvement.

Comments that were received are included and identified below. Disposition of these comments in regard to the JVAP PEA are also included.

Appendix H-I	Maryland Department of the Environment letter dated July 9, 1997
Appendix H-II	Citizen Soldier letter dated July 11, 1997
Appendix H-III	DynPort letter dated July 11, 1997
Appendix H-IV	The Mangi Environmental Group, Inc. letter dated July 12, 1997
Appendix H-V	Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention letter dated July 14, 1997
Appendix H-VI	U.S. Environmental Protection Agency, Office of Enforcement and Compliance Assurance letter dated July 15, 1997



MARYLAND DEPARTMENT OF THE ENVIRONMENT
2500 Broening Highway • Baltimore, Maryland 21224
(410) 631-3000

Parris N. Glendening
Governor

Jane T. Nishida
Secretary

July 9, 1997

Ms. Winifrede L. Fanelli
Joint Project Management Office
568 Doughten Drive, Suite 100
Fort Detrick MD 21702-5040

RE: MDE Identification Number: ES970613-0027
Project: Joint Vaccine Acquisition Program

Dear Ms. Fanelli:

Thank you for the opportunity to review the above referenced project. The document was circulated throughout the Maryland Department of the Environment (MDE) for review, and the following comments are offered for your consideration.

1. If boilers or other equipment capable of producing emissions are installed as a result of this project, the applicant is requested to obtain a permit to construct from MDE's Air and Radiation Management Administration for this equipment, unless the applicant determines that a permit for this equipment is not required under State regulations pertaining to "Permits, Approvals, and Registration" (COMAR 26.11.02.). A review for toxic air pollutants should be performed. Please contact Dr. Justin Hsu, Ph.D., P.E., New Source Permits Division, Air and Radiation Management Administration at (410) 631-3230 to learn about the State's requirements and the permitting processes for such devices.
2. If medical wastes will be incinerated, a permit to construct and a permit to operate the incinerator must be obtained from MDE's Air and Radiation Management Administration. The applicant should contact Dr. Justin Hsu, Ph.D., P.E., New Source Permits Division, Air and Radiation Management Administration at (410) 631-3230 to learn about the State's requirements and the permitting processes for incinerator permits.
3. All x-ray machines in the State of Maryland must be registered. Please contact Mr. Thomas Ferguson, X-Ray Section, Air and Radiation Management Administration at (410) 631-3300 for additional information. Any person or institution that wants to acquire radioactive materials is required to possess a license. Please contact Mr. Carl Trump, Jr., Radioactive Materials Licensing Section, Air and Radiation Management Administration at (410) 631-3300 for additional information.

Ms. Winifrede L. Fanelli
July 9, 1997
Page Two

4. Any above ground or underground petroleum storage tanks which may be utilized must be installed and maintained in accordance with applicable State and federal laws and regulations. Contact the Oil Control Program at (410) 631-3442 for additional information.
5. Any solid wastes, including construction, demolition and land-clearing debris, generated from the subject project must be properly disposed of at a permitted solid waste acceptance facility, or recycled if possible. Contact the Solid Waste Program at (410) 631-3318 for additional information.
6. Underground storage tanks must be registered and installation or removal must be conducted and performed by a contractor certified to install/remove underground storage tanks by the Waste Management Administration in accordance with Oil Pollution and Tank Management, COMAR 26.10. Contact the Oil Control Program at (410) 631-3442 for additional information.
7. The Hazardous Waste Program should be contacted directly at (410) 631-3343 by those facilities which generate, handle, or propose to generate or handle hazardous wastes to ensure these activities are being conducted in compliance with applicable State and federal laws and regulations.
8. The Hazardous Waste Program should be contacted directly at (410) 631-3343 prior to construction activities to ensure that the treatment, storage or disposal of hazardous wastes and low-level radioactive wastes at the facility will be conducted in compliance with applicable State and federal laws and regulations.

Again, thank you for giving MDE the opportunity to review this project. If you have any questions, please feel free to call me at (410) 631-3656.

Sincerely,



Steven Bieber
Clearinghouse Coordinator

cc: Bob Summers, Maryland Department of the Environment
Bob Rosenbush, Maryland Office of Planning

Joint Vaccine Acquisition Program
Final Programmatic Environmental Assessment

Appendix H-I

Maryland Department of the Environment letter dated July 9, 1997

Summary and disposition of comments.

Summary. This letter addresses matters relating to specific environmental considerations within the State of Maryland. It identifies eight (8) specific areas of potential environmental concern or impact and provides Maryland Department of the Environment office phone numbers to be contacted prior to initiation of site specific activities within the State of Maryland.

Disposition. Although the information provided is potentially very helpful if future JVAP operational activities are conducted in the State of Maryland, no revisions of the JVAP PEA are necessary. The JVAP PEA is a programmatic assessment of potential environmental impacts without regard to any particular site, locality or state where operations may be conducted. Future site specific assessments to support DoD JVAP decision making will tier from the JVAP Final Programmatic Environmental Assessment (FPEA). Inclusion of this letter in the JVAP FPEA will assist preparation of any future environmental assessments of JVAP activities that might be proposed to be conducted in the State of Maryland.



175 Fifth Ave. #808
New York, N.Y. 10010
(212) 679-2250

July 11, 1997

Mr. Bruce Kay
Joint Vaccine Acquisition Program
568 Doughten St.,
Ft Detrick, MD 21702-5040

Dear Mr. Kay, (via FAX and Fed Express #5499804461)

This letter is submitted in response to the PVAP's request for public comment on your Draft Programmatic Environmental Assessment for the Joint Vaccine Acquisition Program.

Two of us are physicians with extensive experience working on a host of civilian and military health issues, including vaccinations. The third signator is an attorney with nearly thirty years' experience as a public-interest lawyer and GI/veterans' advocate on a variety of health issues.

First, we want to underscore our deep concern about the very limited period for public comment allowed for this JVAP--slightly more than 30 days. This is much too brief, given the complexity of the issues being addressed. We urge you to extend the time for public comment by at least another ninety days and that you conduct public hearings in the Washington, D.C. area; with adequate public notice. This will allow for the expression of the broadest possible cross section of scientific views on your proposed JVAP.

I. We urge that ultimate authority for developing BW vaccines and related research for prophylactic, protective, and other peaceful uses be immediately transferred to a civilian agency such as the National Institutes of Health or the Centers for Disease Control and Prevention.

We base our recommendation on the following factors:

A) The transfer of control to civilians will remove the risk that somehow scientific research into BW vaccines could be used by the U.S. military to construct biological weapons or to conduct activities which could be construed by other nations as preparation for the conduct of biological warfare. As you know,

such activities are prohibited by the Biological & Toxin Weapons Convention of 1975.

B) The involvement of the U.S. military in clandestine BW research over many years has left the general public and military veterans deeply distrustful. From 1949-69, the Army conducted hundreds of secret, simulated biological warfare attacks across the U.S. Millions of Americans were unwittingly exposed as bacteria were sprayed from autos, boats, suitcases, and even lightbulbs that were tossed on subway tracks. In one infamous incident in 1968, lethal nerve gases were accidentally sprayed 20 miles beyond the boundaries of the Army's Dugway Proving Ground in Utah, killing 6,400 sheep. In that case, the Army refused to acknowledge its involvement for 15 months.

As with other weapons systems, fear of what an enemy might do can feed our military's own designs. It is very important that America is seen internationally as complying with all provisions of the BTW Convention if the treaty's power is to be maintained.

C) Your proposal notes that 150,000 U.S. military personnel received at least one anthrax vaccination and about 8,000 GIs received at least one dose of botulinum toxoid (BT) during the Gulf War. In addition, approximately 250,000 U.S. troops took at least some pyridostigmine bromide (PB).

We are very alarmed by your assertion, at p. 4-18, line 1, that, "there have been no reports of adverse events related to anthrax vaccine received during or since the Gulf War."

You certainly know that nearly 100,000 Persian Gulf war veterans who are suffering from a variety of ailments, have sought medical evaluations from either VA or military medical centers since 1991. It is entirely possible that some of the health problems suffered by some of these veterans are due to a synergistic effect from several different exposures, including the anthrax vaccinations that many received.

The fact is that you cannot say, with any scientific certainty today, that the vaccines given during Operations Desert Shield/Storm had no adverse health effects. Neither the U.S. military, nor any other agency for that matter, has devoted sufficient resources to study these questions. Your willingness to make such unsubstantiated assertions is another reason why we believe a civilian agency, with no conflicts of interest, should be placed in charge of the JVAP.

D) Responsibility for Monitoring of Vaccine Recipients is

another area of concern. Your proposal describes, at p. 2-27, line 30, et al., that military vaccine recipients will be monitored via the Vaccine Adverse Event Reporting System (VAERS). At another point, Med Watch is mentioned. We believe that these two systems, which are administered by the CDC and FDA, have experience only with civilian exposures.

The VAERS and Med Watch monitoring systems are essentially passive reporting systems which rely on vaccine manufacturers or medical staff members to report adverse health reactions experienced by those taking various vaccines. Past experience teaches that with these types of monitoring systems few adverse reactions are reported, especially if there is no pressure from top officials to identify problem areas.

We only have to go back as far as the Gulf War to find evidence that military personnel's vaccinations were not handled in a professional and scientific manner. Many GIs have since reported that they were forced by their military commanders to submit to vaccinations, even though they had experienced adverse reactions to earlier doses.

As we point out below in (E), your position on the issue of informed consent of test subjects is at variance with civilian standards. For many years, extending back to the 1940s, the U.S. military has improperly and unethically exposed its soldiers and sailors to a long list of toxic substances without their consent. Radioactive fallout from nuclear bomb tests, mustard gas, Lewisite, dioxin-laden 2,4,-T in the herbicide "Agent Orange" LSD, and "truth sera" are just some of the substances to which GIs have been recklessly exposed by their military commanders.

At this point, a deep distrust of the U.S. military exists among tens of thousands of military veterans as well as countless other American citizens. The program to develop eighteen new vaccines should be controlled by civilian public health agencies if it is to enjoy broad trust and public confidence.

E) Your proposal's contention that informed consent is not required in all cases, is erroneous and, by itself, should disqualify the U.S. military from control of the JVAP.

We are deeply opposed to your position that informed consent is not required when it's not "feasible or is contrary to the patient's interests." See p. 2-30, line 6.

We believe that obtaining informed consent from those being subjected to any experimental procedure or condition is absolutely

required in every instance. Creating, in advance, a right for experimenters to waive informed consent rules increases the risk that test subjects may be abused or injured.

F) Your proposal also leaves open a possibility for abuse where vaccines are to used or tested outside the United States. At p. 2-29, lines 37-38, you require only "approval for clinical protocols...by host nation authorities." As you know, scientific standards and the quality of medical research and treatment vary widely outside the U.S., especially in underdeveloped nations. For this reason, U.S. regulations covering medical experimentation should be applied and enforced by researchers throughout the world, without regard to national borders.

Recent public revelations concerning serious environmental problems at the Brookhaven National Laboratory demonstrate how conflicts of interests can emerge when any governmental agency is given responsibility for monitoring its own environmental practices. A recent Department of Energy report on Brookhaven activities concluded that its staff of 3,200 was bound by a, "perception that freedom and creativity needed for scientific inquiry are stifled by the discipline needed to prevent accidents or environmental problems." Brookhaven's managers, the DOE review noted, were not rated on their attentiveness to environmental practices, safety or health. (The Lancet, Vol. 349, May 31, 1997).

The situation with the U.S. military is no different. In the past, the U.S. military operated many of its bases without complying with local or federal environmental laws and regulations. In fact, a substantial portion of "Superfund" cleanup funds have had to be allocated to cleaning up de-commissioned military bases.

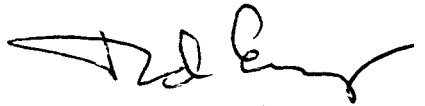
We urge you again to immediately transfer authority over the JVAP from the U.S. military to a civilian agency such as the National Institutes of Health or the Centers for Disease Control and Prevention.

We also reiterate our request that the public-comment period for this JVAP be extended by at least ninety days and that broadly publicized public hearings be held to insure that a broad cross-section of viewpoints are heard on these important issues.

Sincerely yours,

V.S.
Victor Sidel, M.D.

M. Nass
Meryl Nass, M.D.


Tod Ensign, Esq

Dr. Victor Sidel is past President, American Public Health

Association, a co-founder and current co-President, the International Physicians for the Prevention of Nuclear War, which received the 1985 Nobel Peace Prize, and Distinguished University Professor of Social Medicine, Montefiore Medical Center and Albert Einstein College of Medicine, Bronx, N.Y. Sidel has published extensively on public health issues.

Dr. Meryl Nass, has published numerous scientific articles on the subject of anthrax and other vaccines. She is currently on the medical staff of Wing Memorial Hospital, Amherst, MA

Tod Ensign, a lawyer, is director of Citizen Soldier, a non-profit GI/veterans rights advocacy organization. Ensign is co-author of GI Guinea Pigs, author of Military Life: The Insider's Guide, and recently contributed a chapter to Metal of Dishonor: Depleted Uranium Weapons

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Appendix H-II
Citizen Soldier letter dated July 11, 1997

Summary and disposition of comments.

Summary. This letter contains a number of comments. Each is individually identified and referenced by number (i.e., “1”, “2”) and brackets on the text relating to each number. The summary and disposition of each of these comments follow.

Comment 1 - summary. This comment expresses concern that the public comment period was too brief and urges an extension by another 90 days as well as public notification and the conduct of public hearings in the Washington, DC area.

Comment 1 - disposition. An additional comment period of at least thirty (30) days will follow publication and notification of the public availability of the JVAP FPEA and the resulting Finding of No Significant Impact (FNSI). Additional public comments may be submitted during this period and will be reviewed and considered. These considerations will be incorporated into decision making on the JVAP as proposed and on the alternatives to the proposed action.

The JVAP PEA characterizes and assesses the possible and probable environmental consequences associated with the JVAP as proposed and the alternatives considered. The JVAP as proposed and each alternative, except the no action alternative, require full operational compliance with federal, state and local laws and regulations. It is emphasized that, in addition to these laws and regulations, the proposed JVAP development, storage, testing, distribution and disposal of vaccines and related medical materiel for biological defense is to be fully regulated by the U.S. Food and Drug Administration (FDA). Though complex, the proposed and alternative JVAP operations are highly regulated with the deliberate purpose of many of these regulations being the protection of the human environment.

The public comment period for the draft PEA is not required by NEPA but was provided as a means to expand public awareness of the proposed action. While the Army is obviously committed to ensuring public participation in considering environmental consequences, it is felt that neither this letter nor this comment provide sufficient assessment and justification that potential JVAP environmental consequences warrant an extended public comment period. Under NEPA regulations, public hearings—public scoping—are normally conducted when significant environmental impacts have been documented in an environmental assessment and it results in a notice of intent to prepare an environmental impact statement. The JVAP FPEA concludes that the proposed JVAP activities and the alternatives analyzed are not likely to have significant adverse effects upon the quality of the human environment.

Comment 2 - summary. This comment “...urges that ultimate authority for developing BW vaccines and related research for prophylactic, protective and other peaceful uses be immediately

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transferred to a civilian agency such as the National Institutes of Health or the Centers for Disease Control and Prevention.” This is based on several factors.

a. Remove the risk that the U.S. military could use the vaccine research to construct biological weapons or that other nations might believe that the conduct of the program is related to preparation for biological warfare.

b. “The involvement of the U.S. military in clandestine BW research over many years has left the general public and military veterans deeply distrustful. ... It is very important that America is seen internationally as complying with all provisions of the BTW Convention if the treaty’s power is to be maintained.”

c. “The fact is that you cannot say, with any scientific certainty today, that the vaccines given during Operations Desert Shield/Storm had no adverse health effects. Neither the U.S. military, nor any other agency for that matter, has devoted sufficient resources to study these questions. Your willingness to make such unsubstantiated assertions is another reason why we believe a civilian agency, with no conflicts of interest, should be placed in charge of the JVAP.”

d. “Responsibility for Monitoring of Vaccine Recipients is another area of concern. ... At this point, a deep distrust of the U.S. military exists among tens of thousands of military veterans as well as countless other American citizens. The program to develop eighteen new vaccines should be controlled by civilian public health agencies if it is to enjoy broad trust and public confidence.”

e. “Your proposal’s contention that informed consent is not required in all cases, is erroneous and, by itself, should disqualify the U.S. military from control of the JVAP. ... We believe that obtaining informed consent from those being subjected to any experimental procedure or condition is absolutely required in every instance.”

f. “Your proposal also leaves open a possibility for abuse where vaccines are to be used or tested outside the United States. At p. 2-29, lines 37-38, you require only ‘approval for clinical protocols...by host nation authorities’. ...Scientific standards and the quality of medical research and treatment vary widely outside the U.S., especially in underdeveloped nations. For this reason, U.S. regulations covering medical experimentation should be applied and enforced by researchers throughout the world, without regard to national borders.”

Comment 2 - disposition. The comment and following rationale largely relate to matters of Executive Branch policy and procedures and do not specifically or directly address or identify potential environmental consequences of the proposed action or of the identified alternatives. This comment does not alter conclusions or findings of the JVAP dPEA.

The Defense Department’s biological defense programs are conducted in full compliance with the *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological*

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(Biological) and Toxin Weapons and on Their Destruction (BTWC). The President of the United States, as the Chief Executive and Commander in Chief, has ultimate authority and responsibility for these Executive Branch programs. This authority extends through DoD civilian leaders, the Secretary of Defense and the Secretaries of the Military Departments, to the Joint Project Manager of the Joint Vaccine Acquisition Program who is a civil service employee. Like other Executive Branch programs, the DoD biological defense programs are justified to and authorized by the Congress of the United States within the spending authority defined by the Congress. Indeed, the state of medical materiel readiness for biological warfare defense, and in particular vaccine acquisition, has been a continuing high priority and special interest of the Congress since the Gulf War. There has been no evidence presented that transfer of responsibility for these programs to a non-DoD agency [subfactors 2(a) and 2(b)] would significantly alter either U.S. public or international confidence in U.S. compliance with the BTWC or that such a transfer would alter the environmental consequences of JVAP operations.

With regard to potential adverse health effects of biological defense vaccines [subfactor 2(c)], it is true that there is no scientific method that allows the determination that vaccines are absolutely safe—science can only prove that something has had an impact. Data from both military and non-military populations receiving the anthrax vaccine and the botulinum toxoid, pentavalent vaccines, do not support the assertion that administration of these products results in long-term, adverse health effects. The concerns raised in this subfactor were examined in a report by the National Institute of Medicine and are addressed on page 4-20 of the JVAP dPEA. Regardless, there has been no evidence that transfer of program authority would impact the potential for adverse health effects since JVAP vaccines are to be FDA-regulated. These conclusions are supported by both the report of the Presidential Advisory Committee on Gulf War Veterans' Illnesses and the Institute of Medicine. For information related to the resources that are being devoted to Gulf War illnesses, refer to the list of research projects in Appendix F of the report by the Presidential Advisory Committee (<http://www.gwvi.gov>); new research continues to be funded.

The proposed JVAP shall comply with FDA regulations. This is consistent with the comment [subfactor 2(d)] that, "The program to develop eighteen new vaccines should be controlled by civilian public health agencies if it is to enjoy broad trust and public confidence." The FDA is the U.S. authority and responsible regulatory agency for medical product safety and efficacy; DoD cannot impose a separate set of regulations or interfere with FDA regulatory authority. The DoD is committed to ensuring compliance with all FDA requirements.

Regarding informed consent [subfactor 2(e)], the authors' perspectives are at variance with 21 CFR 50.23. Transfer of program authority to another Federal agency would not impact this issue. 21 CFR 50.23 governs waiver of informed consent and states, in general, that waivers may only be granted for use of an Investigational New Drug (IND) when an actual or threatened military exigency exists, and that the health of the individual and safety of other personnel require the use of a particular treatment where withholding treatment would be contrary to the best interests of military personnel. Additionally, in granting a waiver the Commissioner of the

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FDA/HHS must take into account the extent and strength of the evidence of the safety and effectiveness of the IND for the intended use; the context in which the drug will be administered; the nature of the disease or condition for which the preventive or therapeutic treatment is intended; and the nature of the information to be provided to the recipients of the drug.

Clinical protocols conducted in a country other than the U.S. [subfactor 2(f)] require review and approval of host country authorities *in addition to* compliance with U.S. regulations for protection of human subjects as cited previously in the referenced paragraph. The JVAP FPEA is revised to clarify this point by changing the last sentence of the first paragraph in section 2.7 to read, “In addition to compliance with U.S. regulations for protection of human subjects, review and approval for clinical protocols must be obtained by host nation authorities when a protocol is conducted in a country other than the U.S.”

Comment 3 - summary. This comment asserts that “...conflicts of interests can emerge when any governmental agency is given responsibility for monitoring its own environmental practices.” It further asserts that past U.S. military operations were not in compliance with local or Federal environmental laws and regulations.

Comment 3 - disposition. No change is required since it is proposed that the JVAP be conducted in full compliance with Federal, state and local environmental laws and regulations. Proposed execution of JVAP operations in the preferred and one other alternative is to be conducted by private sector contractors and not by DoD employees. Further, the concern about operational and environmental conflicts of interest is not unique to any agency and ignores Federal, non-DoD, and state authority for environmental regulation and compliance. The JVAP will be conducted in full compliance with Federal, state, and local environmental laws and regulations and will be monitored by Federal agencies (EPA, FDA, OSHA), state and local agencies, as well as the DoD.



2000 Edmund Halley Drive, Reston, Virginia 20191-3436

DPEA: 97-1
July 11, 1997

Mr. Bruce Kay
JVAP-PMO
568 Doughten Drive, Suite 100
Fort Detrick, MD 21702-5040

Reference: JVAP-Draft Programmatic Environmental Assessment

Dear Mr. Kay:

On behalf of DynPort, I am pleased to submit our comments on the above referenced document. The DynPort team appreciates the opportunity to provide comments that support the Joint Program Office in this critical national defense program.

If you have any questions regarding this submission, please do not hesitate to call me at (703) 264-9301, or Mr. Tom Walter, my Vice President for Contracts and Pricing, at (703) 254-8734.

Sincerely,
Carl H. McNair, Jr.
Chairman
Board of Managers, DynPort

Signed on his behalf:

Mr. Thomas Walter
Vice President - Contracts and Pricing
DynCorp



2000 Edmund Halley Drive, Reston, Virginia 20191-3436

DynPort is pleased to offer its comments on the JVAP-DPEA which was made available for public input. DynPort is an organization formed by DynCorp, a \$1 billion technical services company with a 50-year reputation of excellence in technical contract management for DOD, and Porton International, a U.K.-based pharmaceutical company with direct experience of managing DOD vaccine development programs. DynPort was formed with the sole mission of ensuring the Joint Program Office a successful JVAP contract. The DynPort management team, located within the program office to ensure complete and rapid response to JPO, have direct experience in managing vaccine development, production, licensing, storage, and distribution combined with a demonstrable capability to work with the medical biological defense products (MBDP) that will be the core of the JVAP contract. DynPort has assembled a team that possesses exceptional depth and breadth of experience in vaccine and biotechnology product development and production. Based on the corporate experience of DynCorp and Porton in environmental compliance for a wide range of company activities, extensive experience providing technical and policy support to the Government on environmental programs and over a decade of successful performance in the MBDP arena, DynPort is well-qualified to assess and comment on the draft PEA.

DynPort Assessments:

- (i) The proposed FONSI for JVAP activities is appropriate and sustainable based on the fact that current and proposed JVAP activities have been and will continue to be performed without significant environmental impacts.
- (ii) The performance of the JVAP contract as outlined in Alternative I (the preferred alternative) provides the best approach and enables the DOD to utilize industry standards and best commercial practice in performance of the required spectrum of JVAP activities.
- (iii) The use of a “tiered approach” which will enable future, as yet undefined, activities which will be undertaken at “uncertain sites of program execution” to be properly assessed and incorporated into the JVAP EA is an appropriate action. This approach will also permit the JVAP to maintain compliance with changes in NEPA and AR 200-2 where they are relevant to future JVAP activities.

DynPort Experience of issues related to JVAP-DPEA

- (i) The JVAP-DPEA identifies that “potential risks to JVAP laboratory and production workers, public health and the environment are and will be mitigated by the appli-

cation of required work practice and engineering controls which direct the safe handling, use and disposal of etiologic agents and other potentially hazardous materials." These are standards of operation that are well established in the pharmaceutical industry and their proven safety programs. Both of the founding partners of DynPort have direct experience in the application of safety programs in performance of activities directly related to JVAP. Furthermore, DynPort management have experience in management of programs which are identical to JVAP in their requirement to utilize infectious (hazardous) etiologic agents. In particular, Porton have performed DoD contracts involving the development of vaccines based on growth of botulinum organisms in BL-3 facilities. DynCorp have been responsible for the development of viral vaccines for human use in BL-3 facilities for over two decades. This experience, allied to the incorporation of industry standards for safety, will ensure minimal environmental risk in performance of JVAP.

- (ii) DynPort concurs with the DPEA that effective contract performance and environmental compliance in JVAP is best established by a contractor's program office that is experienced in the management of vaccine development, production, licensing, storage, and distribution. The DynPort team was formed with this direct experience of appropriate, similar, activities to JVAP uppermost in the capabilities of the Program Office. Furthermore, in selecting its team members DynPort developed a team that has a proven capability in meeting FDA (and DoD) requirements for JVAP activities. This is evidenced by Greer Laboratories Inc., (Lenoir, NC) who are responsible for the production and supply of the Plague Vaccine USP that is currently used by the DoD. The use of FDA-compliant organizations will ensure that the facilities, resources and skilled personnel performing JVAP have proven capability to meet environmental needs as codified through NEPA and AR 200-2.
- (iii) The utilization of experienced (FDA-compliant) manufacturers for JVAP contract performance conforms to a trend that is becoming increasingly prevalent in the pharmaceutical industry. DynPort management is very familiar with these types of operation, i.e. contract manufacture, managing similar activities in fields related to JVAP products. It is DynPort's experience that this trend is identified and supported by the FDA both in terms of the speed of review of license applications for "known" contract manufacturers and the recent changes that have been proposed for FDA regulations. The latter is demonstrated by the proposed easing of the current requirements for ELA's for biological products. The use of contract manufacturers in the context of current and future EA's will ensure minimal environmental impact and adherence to the regulations at Federal, state and local levels. The contract manufacturers that will be used by DynPort will already have in place both relevant EA's and appropriate safety programs for JVAP type activities. This is demonstrated by DynPort's proposed use of Covance (Corning-Bio, Durham, NC) who provide the largest (and newest) contract facilities in the USA for development and manufacture of recombinant biological products such as

those described in the JVAP RFP. This approach, the use of pharmaceutical industry standards, to the performance of the JVAP contract thus minimizes the risk of adverse environmental impacts for JVAP activities.

- (iv) As stated in the DPEA "Public opinion toward a proposed action must be considered to the maximum extent practicable in accordance with NEPA and AR 200-2". DynPort wholeheartedly supports the aims of the regulations and has been active, through its members, in implementing the directives. For nearly two decades our team members have been responsible for, and experienced with, the involvement of public input in matters relating to the perceived biotechnological risks. A DynPort Board officer designed and led a series of initiatives for public input at the U.S. Congress Office of Technology Assessment beginning as early as 1979. As a result much of the public and Congressional concern was addressed through the OTA reports. As deliberate and accidental threats from BD research continue to be a concern, DynPort believes that the prime contractor must be proactive in addressing the issues.

Joint Vaccine Acquisition Program
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Appendix H-III
DynPort letter dated July 11, 1997

Summary and disposition of comments.

Summary. DynPort's letter is supportive of the JVAP dPEA and its findings. "DynPort was formed with the sole mission of ensuring the Joint Program Office a successful JVAP contract." DynPort assessed that a proposed JVAP PEA FNSI is appropriate; that the preferred alternative provides the best approach; and that the use of a tiered approach for environmental assessments is appropriate.

Disposition. Comments support the JVAP PEA and its conclusions and no changes are necessary as a result.

THE MANGI ENVIRONMENTAL GROUP, INC.
701 W. Broad St., Falls Church VA 22046
703 534 2484 Fax 534 2487

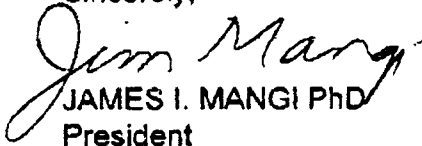
12 July 1997

Joint Vaccine Acquisition Program
Program Management Office
Attn: Bruce Kay
568 Doughten Drive Suite 100
Fort Detrick MD 21702

Dear Mr. Kay:

As a former Army Chemical Officer, with a PhD in Biological Sciences, and 24 years of experience with NEPA, I am enclosing some comments on the JVAP DPEA.

Sincerely,


JAMES I. MANGI PhD
President

JVAP-DPEA - Comments

In reviewing the information provided in the JVAP-DPEA it is clear that the conclusion of the DA that *"implementing JVAP in its current and planned scope (Alternative 1, the preferred alternative will likely result in only negligible or minor environmental impacts"* is an accurate assessment and should enable JVAP to proceed as planned. There are however issues that are raised by the DPEA which could impact on the proposed contract and which merit further consideration. It is possible that these have been addressed in the resolution of the award of the contract - they are included here to record them in the context of their impact on any future EA.

(a) The Need to Expand the Medical BD Industrial Base.

"The current medical biological defense industrial base for the production of biological defense vaccines is inadequate to, achieve the needs identified by the DoD" (Page 1-3, lines 13-15). This indicates a need for additional capability to meet the needs of the proposed program. In considering the *"Alternatives (III/IV)"* the DA identify that renovation or new construction will be prohibitively expensive and result in a delay in providing the required products (Pages 4-5, 4-6). There is therefore a need to utilize *"existing operational facilities"* (Page 4-5, line 43). Any such facilities must meet or exceed the standards described in the DPEA in order that they be considered acceptable for JVAP performance. This apparent capability gap must therefore be bridged using facilities that are already operational but which are not currently performing DA contracts in support of BD vaccine products.

Given the limitations that apparently exist in respect of the organizations previously, or currently, utilized by the DA the involvement of organizations not previously part of the BD vaccine program would seem to be desirable - the prime candidates being existing vaccine manufacturers. Such organizations would provide immediate and compliant facilities to meet the urgent requirements that JVAP seeks to address. The DA would be assured of their minimal environmental impact based on their annual inspection by the FDA for the purposes of maintaining their *"Establishment Licenses"* and their need to meet all Federal, state and local legislation for existing products that are similar to those that are the subject of JVAP. Furthermore, because of their continued involvement in manufacture and supply of FDA-licensed products for commercial, as well as putative DA, needs they will continue to invest in meeting the requirements of compliance with environmental legislation without the need for substantial DA financing.

(b) The Use of Existing Pharmaceutical (Vaccine) Manufacturers.

"the potential for significant adverse environmental impacts is minimized by effective application both Federal, State and local laws and regulations and of pharmaceutical industry practices and procedures". (Page E-4 (Appendix), lines 21-22). This statement indicates the value of utilizing organizations that are fully compliant with relevant statutory laws and the standards imposed by the highly regulated pharmaceutical industry i.e. existing FDA-licensed manufacturers of medical (vaccine) products.

Furthermore the statements which reinforce the need to provide products that *"ensure that service members are afforded the same level of safety and protection as the civilian populace for similar medical products"* (Page E-15, lines 2-6) lead to the conclusion that the best choice of organization(s) for JVAP would be one, or more, of the existing manufacturers of FDA-licensed vaccines.

The DPEA identifies that it is *"unlikely that private sector pharmaceutical companies would invest in their (biological defense vaccines) development and production"* (Page 1-3, lines 19-20, text in parentheses added). The JVAP provides for development of the products and will presumably meet production costs thus removing the key concerns of "industry" and enable them to become participants in the JVAP contract.

It would appear that the JVAP contract could thus best be performed using existing vaccine (or biological products) manufacturers to provide the required skills, resources and facilities and, through a proven track-record of compliance with regulatory and statutory regulations, ensure that the environmental impact will be minimal. This approach would appear, in addition, to ensure immediate availability of facilities capable of manufacturing the JVAP products thus providing the best possible chance of the required vaccines being made available at the earliest opportunity.

This approach, i.e. the outsourcing, or contract manufacture, of pharmaceutical products is becoming increasingly prevalent in industry. The current and future proposal changes in FDA regulations reflect (and support) the shift to utilizing organizations with proven track-records of successful manufacture of pharmaceutical products. The FDA is increasingly seeking to have products manufactured by "expert" organizations a trend that is reflected in the growth of contract manufacturing operators. The FDA acknowledges the value in having manufacture by dedicated production operators and accepts these "pharmaceutical industry" organizations as the norm. The recognition by DOD that JVAP is best performed by such organizations and that reliance on industry standards provides the best option for future FDA licensure relates directly to this DPEA and the resulting FONSI. If JVAP is performed by existing FDA licensed industrial organizations the EA's will be readily performed and, as a result of the concern of industry in maintaining commercial manufacturing operators, will almost certainly result in a FONSI for proposed JVAP activities.

(c) The Additional Requirements Imposed by Participation in JVAP

"General Safety Requirements" Section 2.5.2

It is clear from the previous discussions (see above) that the use of existing FDA-licensed facilities will minimise any potential environmental impact in performing the proposed JVAP work. There are however additional requirements that are imposed by the DoD which potential contractors must also meet or exceed. *"All activities of a hazardous nature.....are governed by the Army Safety Program (AR 385-10).."* Page 2-18, lines 33-35.

"The Army Safety Program for all aspects of the Biological Defense Program is established in AR-385-69, Biological Defense Safety Program (32 CFR Parts 626,627)." Page 2-18, lines 38-40.

"Additional safety requirements include compliance with guidelines for the design, construction and maintenance of safe laboratory facilities. These include...." Page 2-18, Lines 43-45; Page 2-19, Lines 1-7.

These require that the JVAP contractor has as a minimum a working knowledge of the cited regulations and the capability to ensure that selected subcontractors are properly inspected to ensure compliance prior to subcontract award and the commencement of work. The Contract Office of the JVAP contractor must therefore be sufficiently expert to ensure proactive rather than reactive interactions with its subcontractors, the FDA and the DoD (see paras. (d),(e),(f)). The use of existing (FDA-licensed) facilities that require no (or very limited) additional renovation or modification and which can be managed through an effective JVAP contractors' program management office (see paras. (d),(e),(f)) would appear to offer the best solution. In the event that this is not feasible (see below) the best alternative would appear to be the use of facilities which can be readily modified or renovated to meet JVAP contract needs and which have a proven track-record of acceptance (licensure) by the FDA as they have, through demonstrable success, the necessary skills and knowledge to ensure that they will provide resources, facilities etc. that can meet the required standards of the FDA and relevant Federal, state and local legislation.

The use of facilities that were not designed to function as pharmaceutical facilities, and which are not operated according to normal pharmaceutical industry practices will likely pose programmatic, and possibly environmental problems (e.g. MBPI Page iii and Appendix E). The use of existing industry would appear to be more acceptable and in utilizing such capabilities the DoD will progress the JVAP contract with minimal investments in time and cost and with maximum assurance of NEPA compliance.

(d) The JVAP Contractor - Scope of Operation

"The primary objective of the JVAP is to develop, produce, store, test and field sufficient quantities of U.S. Food and Drug Administration (FDA) licensed vaccines to

implement U.S. government policy for protecting its armed forces against death and disease resulting from biological warfare agents" Page ii, Lines 20-23.

"Significant management, regulatory affairs, and production challenges are associated with this program because of the number of different biological defense products included and the significant requirements of the FDA" Page 2-8, Lines 6-8.

"The prime systems contractor will use currently available information and materials from the existing DoD.....The Prime systems contractor will provide allnecessary to accomplish all specified tasks." Page 2-8, Lines 17-22.

From a technical standpoint it is clear from the above noted statements that the JVAP contractor will necessarily be - familiar with the existing, and historic, activities of the DoD, be capable of assimilating previously performed work and resultant products into FDA-licensed facilities and plan and perform all tasks needed to successfully develop the BD products into licensed vaccine products (including performing the work in licensed facilities). This is in itself a significant undertaking requiring a fully integrated team of professional managers preferably with experience of the DoD, and other similar products. The JVAP contractors' program management office must therefore be designed to be proactive in dealing with all of the required activities including, FDA, DoD, the public and its subcontractors. The relationship with the FDA will be a key element and a working knowledge of CBER is clearly an advantage. The choice of an effective contractor with these skills will be critical to the future success of JVAP.

In addition to the above the DPEA highlights the requirement that the JVAP contractors' program management office is proactive in all aspects of environmental compliance throughout the performance of JVAP activities. The fact that in addition to programmatic EA issues there will be site-specific EA means that the JVAP contract will require effective management of all environmental matters. Furthermore, ensuring that these activities do not restrict the planned JVAP program of work will necessitate their inclusion in the planning process. The successful contractor should therefore have all the required skills in the JVAP contractors' program management office. this will also provide a single point of contact on environmental matters for the JPBD PM who has *"primary responsibility for directing, managing and administering....."* Page 2-8, Lines 1-4.

In order that the full spectrum of JVAP activities are performed in compliance with NEPA requirements it will entail the JVAP contractors management office adopting a flexible approach which is based on rigid performance criteria coordination by the JVAP contractor of the range of contract activities using strict criteria for compliance with federal, state, and local legislations will ensure that environmental issues are dealt with proactively rather than in response to identified problems. It would appear that coordination of coherent, successful (FDA - licensed) subcontractor operations rather than development of existing or new (unlicensed) operations will reduce risk in environmental issues (and contract performance). The development of

operations, existing or new, will require investment in time and money and increase the risk in both environmental and programmatic elements of the proposed JVAP contract.

(e) The JVAP Contractor - Interaction with the FDA

The JVAP contract in focusing on FDA-licensure of the vaccine products will require ongoing dialogue with the FDA on all matters concerning the products. The FDA will also act as the lead agency on environmental issues where there are "*..potential environmental impacts associated with the manufacture and use of the product*" Page 2-14, Lines 24-25. The issue will initially be addressed in the Product License application made for the product - direct experience of the FDA (CBER) requirements is therefore desirable in the JVAP contractors' program management office in order that the submission is properly prepared and requires minimal, if any, additional information thus minimizing the delays in contract performance.

The FDA review of license applications includes extensive review of the environmental assessment (EA) developed for the proposed product. In the past few years the FDA has demonstrated increased attention to the EA element of its review of license applications. The license application must be properly submitted in respect of the EA if there is not to be a resultant loss of time and delay in product licensure. It is therefore important that the environmental issues and requirements are properly coordinated with the FDA requirements to ensure effective review when the information is submitted in the license application. The availability of dedicated personnel in the JVAP contractors program management office will be of great value in this regard. Given the scope of the operations that will be performed in JVAP and is clear that a "reactive" approach will inevitably lead to delays as notified problems are dealt with by the contractors office. A more productive approach would identify and develop responses in a "proactive" manner, developing solutions in submissions to the various agencies and organizations rather than responding to notification of problems or deficiencies.

The JVAP contractors management office should preferably be experienced in the types of program required by DOD (JVAP), be knowledgeable of the agents and the problems posed by them in respect of EA's and fully coordinated in a collation and submission of environmental (NEPA) and regulatory (FDA) required documentation.

It is an essential requirement both for indirect and direct FDA concerns, as well as broader NEPA requirements, that the JVAP contractors program management office provide oversight and expertise to all environmental, healthy and safety issues for the entire program team including subcontractors. Experienced, dedicated personnel within the contract office would maintain the necessary interaction with the team members developing a common framework

for JVAP reporting, effective compliance to NEPA requirements and response capability and oversight for issues critical to FDA licensure of JVAP products.

(f) The JVAP Contractor - NEPA Compliance and Interaction with the Public

The JVAP contractors' program management office will require ongoing, detailed dialogue with a series of governmental agencies to ensure full compliance with the requirements of NEPA. In addition there will be a requirement to inform the public at various levels of the contract activities that are to be performed.

In respect of the interaction with NEPA the composition of the JVAP contractors' program management office should reflect this requirement and provide all of the necessary skills, resources and facilities to properly perform the required elements. In addition the JVAP contractors' program management office should have access, possibly through consultants but preferably through participating organizations, to personnel capable of performing audit and help in undertaking any required corrective action at the site of the proposed subcontractors.

In developing the operating plan for the JVAP contractors' program management office the need for effective interaction with the public will need to be fully assimilated. If the proposed subcontractors have been performing similar tasks to those proposed under JVAP this activity will likely be relatively simple. If, however, the activities are to be performed at sites not previously used for "JVAP-type" activities the public involvement may be substantial and require significant resources

As members of their local communities, existing manufacturers will provide input, either directly or as members of local business organizations and/or trade associations, into all aspects of the legislative process, including the formulation of environmental regulations. The future of existing manufactures depends on their ability to respond to present and future legislative initiatives in a proactive manner.

One area of particular relevance to performance of JVAP will be the evolving regulations in respect of transport of etiologic agents and products derived from these agents. It will be important that in performing JVAP, utilizing the approach outlined as the preferred alternative, there will be multiple sites involved in manufacture of BD vaccine products. In order that the products can be readily transported for storage and future use by medical teams it will be essential that the JVAP contractor is fully versed in the existing, and possible future, legislation concerning transport of JVAP required materials. Furthermore, the transport of JVAP products will be regulated by FDA in its requirements for storage, handling etc. for medical products. Thus the JVAP contractors management office must be fully conversant and experienced in the full spectrum of regulations for effective contract performance. In order that this is readily accomplished the JCMO should be of sufficient size and capability to

meet existing and future needs through the work of personnel dedicated to JVAP contract performance.

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Appendix H-IV
The Mangi Environmental Group, Inc. letter dated July 12, 1997

Summary and disposition of comments.

Summary. These comments support the JVAP PEA conclusion as an accurate assessment. It goes on to expand and reinforce a number of points emphasized in the JVAP PEA and in the Statement of Objectives in the JVAP RFP.

Disposition. Comments support the JVAP PEA conclusions and the preferred alternative. No changes are necessary.



Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30341-3724
July 14, 1997

Joint Vaccine Acquisition Project
Management Office, JVAP-PMO
ATTN: Mr. Bruce Kay
568 Doughten Street
Fort Detrick, Maryland 21702-5040

Dear Mr. Kay:

We have completed our review of the Draft Programmatic Environmental Assessment (DPEA) for the Joint Vaccine Acquisition Program. We are responding on behalf of the U.S. Public Health Service. Technical assistance for this review was provided by the National Center for Infectious Diseases, Centers for Disease Control and Prevention.

We believe this DPEA has addressed our potential concerns, and we have no specific comments to offer at this time. Thank you for the opportunity to review and comment on this draft document. We would appreciate receiving a copy of the Final EA when it becomes available, and any future environmental impact statements/assessments which may indicate potential public health impact and are developed under the National Environmental Policy Act (NEPA).

Sincerely,

Kenneth W. Holt, M.S.E.H
Special Programs Group (F29)
National Center for Environmental Health

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Appendix H-V

**Department of Health and Human Services, Public Health Service, Centers for Disease
Control and Prevention letter dated July 14, 1997**

Summary and disposition of comments.

Summary. The comments identify that technical assistance for the review was provided by the National Center for Infectious Diseases, Centers for Disease Control and Prevention. It states that the JVAP dPEA addresses their potential concerns and that no specific comments are offered at this time.

Disposition. No changes are necessary.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 15 1997

OFFICE OF
ENFORCEMENT AND
COMPLIANCE ASSURANCE

Joint Vaccine Acquisition Project Management Office
JVAP-PMO
(Attn: Mr. Bruce Kay)
568 Doughten Street
Fort Detrick, Maryland 21702-5040

Dear Mr. Kay:

The Environmental Protection Agency (EPA) has reviewed the Draft Programmatic Environmental Assessment (EA) for the Joint Vaccine Acquisition Program (JVAP). Our review is provided pursuant to Section 309 of the Clean Air Act. We believe that the process of using a programmatic EA and then tiering documents to site specific National Environmental Policy Act (NEPA) documents is appropriate. This draft EA assesses the environmental issues associated with the broad research, development, testing, and implementation of the JVAP.

Because the draft EA primarily discusses the action on a programmatic level, rather than on the operational or site specific level, we have limited our review to the broader issues involving the action. In general, we believe this document provides a comprehensive analysis of the variables which need to be considered prior to the siting and construction of vaccine facilities. It is our understanding that the programmatic document will be tiered into site specific documents to accommodate the unique environments at each site. These subsequent documents will analyze the environmental impacts specific to each site.

We believe that by addressing the following comments, the EA will provide a clearer understanding of the JVAP:

Page 1-1, para. 1, states that the JVAP operations encompass the life cycle of the vaccine. This indicates that the draft would include cradle to grave information about the vaccines. However, the document does not discuss the shelf-life of the product, nor the disposal of the biological materials. On page 1-4, you reference an earlier programmatic EIS, which examined biological defense vaccine development and the disposal and transport of biohazardous materials. We recommend that you include a summary in the final draft which discusses the contents of that EIS including the disposal and transport of the biological materials as required under the Resource Conservation and Recovery Act.

Page 2-21, para. 1, we recommend that where waste waters cannot be conveyed by piping, onsite management of wastes should follow applicable regulations.

Page 2-25, the first sentence which reads, “such waste may be disposed of as ‘normal’ trash” requires further explanation. It is unclear from this statement how you would handle mixed waste, which cannot be disposed under Subtitle D of RCRA.

Page 2-25, line 23, regarding the citations for RCRA should include RCRA permitting and State authorization regulations found in 40 CFR Parts 270 and 271. Also, a review should determine whether applicable cites should include underground storage tank regulations (40 CFR Part 280), used oil (40 CFR Part 279), or universal waste (40 CFR Part 273).

Page 2-27, we recommend including telephone numbers of monitoring agencies.

Page 4-7, section 4.4.5 re: groundwater: we were pleased to see emphasis placed on RCRA with regard to groundwater protection. It also should be noted that in addition to groundwater protection from sources mentioned, RCRA also protects against the mismanagement of hazardous wastes from production operations. In general, RCRA protects human health and the environment. Although groundwater is one critical pathway, there are many other pathways for which RCRA provides protection. We recommend expanding your discussion to include these other elements.

Page 4-7, section 4.4.5, 2nd para., 2nd sentence. We recommend including additional language after “hazardous wastes sites,” to the effect: as well as the mismanagement of production operations which generate hazardous waste.

Page 4-8. 1st para, 2nd sentence. There does not appear to be adequate information to draw the conclusion that significant impact to groundwater will be eliminated. We recommend that you provide additional information to back the statement or eliminate the word significant.

Page 4-16, section 4.4.18.2. A statement is made that there is small risk to workers associated with the development and production of vaccines. There is potential for risk to workers which is managed or minimized by the level of training and safety. We recommend that you address this concern by discussing how the risk is minimized. Similarly, we recommend adding discussion on how you will facilitate emergency planning, what groups you will involve, and how you will comply with Title III of SARA, involving Community Right to Know.

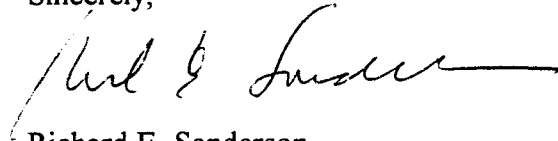
Page 5-1, section 5. We are concerned that the stated principal conclusions are overly broad and hopeful. Based on the content of this report, it is difficult to reasonably draw such conclusions without specific facts. For example, on page 5-1, sentence 2 states “...the preferred alternative has not and will not (emphasis added) result in significant adverse environmental impacts. We recommend that the emphatic “will not” be changed to: is not expected to result...” or that you provide information to support your conclusion.

Page 7-1. We recommend expanding your list of agencies for consultation and review to

include (1) the U.S. EPA, OSWER, Environmental Response Team Center, Edison, NJ, and U.S. EPA, OECA, Office of Federal Activities; (2) Agency for Toxic Substance and Disease Registry; (3) PHS, Center for Disease Control, and (4) OSHA.

We appreciate the opportunity to comment on the draft environmental assessment and welcome the opportunity to review the final EA. Please include us on your mailing list. The staff contact for this review is Marguerite Duffy. She can be reached at (202) 564-7148.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard E. Sanderson", with a long horizontal flourish extending to the right.

Richard E. Sanderson
Director
Office of Federal Activities

Appendix H-VI

**U.S. Environmental Protection Agency, Office of Enforcement and Compliance Assurance
letter dated July 15, 1997**

Summary and disposition of comments.

Comment 1 - summary. These comments support the use of a PEA and tiering documents to site specific assessments. The letter further states, “In general, we believe this document provides a comprehensive analysis of the variables which need to be considered prior to the siting and construction of vaccine facilities. Comments are then offered with the intent of providing a more clear understanding of the JVAP. Discussion and disposition of these specific comments follow.

Comment 1 - disposition. Clarifications are required and these follow each of the specific comments.

Comment - 2 summary. “Page 1-1, para. 1, states that the JVAP operations encompass the life cycle of the vaccine. This indicates that the draft would include cradle to grave information about the vaccines. However, the document does not discuss the shelf-life of the product, nor the disposal of the biological materials. On page 1-4, you reference an earlier programmatic EIS, which examined biological defense vaccine development and the disposal and transport of biohazardous materials. We recommend that you include a summary in the final draft which discusses the contents of that EIS including the disposal and transport of the biological materials as required under the Resource Conservation and Recovery Act.”

Comment 2 - disposition. Storage and stability testing of vaccines are discussed in section 2.4.5.2 and this is relevant to the issue of shelf-life which is product lot specific and dependent on testing (e.g., JVAP dPEA, page 2-16, line 40). The use, handling and disposal of etiologic agents are discussed in section 2.5.4, beginning on page 2-20 of the JVAP dPEA.

Comment 3 - summary. “Page 2-21, para. 1, we recommend that where waste waters cannot be conveyed by piping, onsite management of wastes should follow applicable regulations.”

Comment 3 -disposition. The sentence on p. 2-20, line 36 will be changed to read “All wastewater originating from laboratories and production suites and containing potentially infectious materials will be decontaminated on site by physical or chemical means in accordance with Federal, DA, DoD, state and local regulations.”

Comment 4 - summary. “Page 2-25, the first sentence which reads, “such waste may be disposed of as ‘normal’ trash” requires further explanation. It is unclear from this statement how you would handle mixed waste, which cannot be disposed under Subtitle D of RCRA.”

Comment 4 - disposition. The phrase “normal” trash will be changed to read “routine solid waste.” As discussed on page 2-24, line 34, radioactive material contaminated or potentially

Joint Vaccine Acquisition Program
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contaminated with infectious material is first sterilized by chemical treatment prior to disposal as radioactive waste. This sentence will be altered to read “Radioactive material including mixed waste...”

Comment 5 - summary. “Page 2-25, line 23, regarding the citations for RCRA should include RCRA permitting and state authorization regulations found in 40 CFR Parts 270 and 271. Also, a review should determine whether applicable cites should include underground storage tank regulations (40 CFR Part 280), used oil (40 CFR Part 279), or universal waste (40 CFR Part 273).”

Comment 5 - disposition. The sentence will be modified as follows, “All activities conducted in implementing the proposed actions must comply with Federal hazardous waste regulations (40 CFR Parts 260-266), applicable state and local hazardous waste laws, DOT hazardous materials regulations (49 CFR Part 171), Federal regulations governing occupational exposure to hazardous materials (29 CFR Part 1910), RCRA permitting and state authorization regulations (40 CFR Parts 270 and 271), regulations governing underground storage tanks (40 CFR Part 280), used oil (40 CFR Part 279), and universal waste (40 CFR 273).”

Comment 6 - summary. “Page 2-27, we recommend including telephone numbers of monitoring agencies.”

Comment 6 - disposition. Your comment is noted; however, phone numbers will not be included since they are subject to change and potentially contribute to confusion and not clarification of relevant environmental issues.

Comment 7 - summary. “Page 4-7, Section 4.4.5 re: groundwater: we were pleased to see emphasis placed on RCRA with regard to groundwater protection from sources mentioned. It should also be noted that in addition to groundwater protection from sources mentioned, RCRA also protects against the mismanagement of hazardous wastes from production operations. In general, RCRA protects human health and the environment. Although groundwater is one critical pathway, there are many other pathways for which RCRA provides protection. We recommend expanding your discussion to include these other elements.”

Comment 7 - disposition. The following parenthetical sentence will be added to the first sentence of page 4-7, lines 31-34: “(Adherence to RCRA provisions for management of hazardous wastes and solid wastes are discussed in, respectively, Section 2.5.4.4 and Section 2.5.6).”

Comment 8 - summary. “Page 4-7, Section 4.4.5, 2nd para., 2nd sentence. We recommend including additional language after “hazardous waste sites” to the effect: as well as the mismanagement of production operations which generate hazardous waste.”

Comment 8 - disposition. Your comment is noted. The wording will be changed as recommended.

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Comment 9 - summary. “Page 4-8, 1st para., 2nd sentence. There does not appear to be adequate information to draw the conclusion that significant impact to groundwater will be eliminated. We recommend that you provide additional information to back the statement or eliminate the word significant.”

Comment 9 - disposition. On page 4-8, line 6, the sentence will be revised as follows, “...groundwater resources will mitigate impacts to groundwater at the sites of...”

Comment 10 - summary. “Page 4-16, Section 4.4.18.2. A statement is made that there is small risk to workers associated with the development and production of vaccines. There is potential for risk to workers which is managed or minimized by the level of training and safety. We recommend that you address this concern by discussing how the risk is minimized. Similarly, we recommend that you add discussion on how you will facilitate emergency planning, what groups you will involve, and how you will comply with Title III of SARA, involving Community Right to Know.”

Comment 10 - disposition. Work practice controls and special engineering features used in the conduct of these operations which minimize the potential risk to workers was discussed in Section 2.5 (Environmental Safety Policies and Procedures, p. 2-18 through 2-28). A parenthetical reference to this section will be added to the sentence on p.4-16, line 33.

The following paragraph will be added after the first paragraph of Section 4.4.18.2:

“Requirements regarding emergency planning and reporting on hazardous and toxic chemicals will be followed, including The Emergency Planning and Community Right-to-Know Act of 1986 (Title III, SARA). Contractors must provide the PM JVAP with plans for communicating and coordinating with local emergency personnel including police and fire officials regarding the potentially hazardous materials used at the facility (see Section 2.5.3). Contractors are also required to have current MSDSs for the chemicals in use (see Section 2.5.6).”

Comment 11 - summary. “Page 5-1, Section 5. We are concerned that the stated principal conclusions are overly broad and hopeful. Based on the content of this report, it is difficult to reasonably draw such conclusions without specific facts. For example, on page 5-1, sentence 2 states “...the preferred alternative has not and will not (emphasis added) result in significant adverse environmental impacts. We recommend that the emphatic “will not” be changed to: is not expected to result or that you provide information to support your conclusion.”

Comment 11 - disposition. Your comment is noted. The wording will be changed as recommended.

Joint Vaccine Acquisition Program
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Comment 12 - summary. “Page 7-1. We recommend expanding your list of agencies for consultation and review to include (1) the U.S. EPA, OSWER, Environmental Response Team Center, Edison, NJ; the U.S. EPA, OECA, Office of Federal Activities; (2) Agency for Toxic Substance and Disease Registry; (3) PHS, Center for Disease Control, and (4) OSHA.”

Comment 12 - disposition. The list of agencies reviewing the JVAP FPEA will be expanded to include those recommended.